IN THE
UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

DAVID S. ZINK et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	No. 2:12-CV-4209-NKL
	)	
GEORGE A. LOMBARDI et al.,	)	
	)	
Defendants.	)	

FIRST AMENDED COMPLAINT

Defendants have continued to hide, change, and obfuscate the means by which they intend to kill the plaintiffs in order to prevent counsel whom this Court has appointed from obtaining the expert assistance that the indigent death-sentenced plaintiffs need to present their case with the precision of which they are capable. On November 20, 2013, the defendants used the latest variant of their plan to attempt to moot the case. They did so when the plaintiffs had a live motion pending to address grounds for a stay that this Court had expressly reserved and that no other court had addressed. In a phone conference on November 26, 2013, this Court granted the plaintiffs' motion for leave to amend and authorized them to go beyond the matters adduced

in the complaint they tendered as an exhibit to the motion for leave to amend. Despite the high likelihood that the defendants' dark lights of perverted science will continue to conjure changes in protocols or their implementation on the eve of the next execution dates they have secured and are able to procure, the plaintiffs, by and through counsel, now state and allege all as follows for their causes of action.

Nature of the Action

1. Petitioners brought this action in the Circuit Court of Cole County on June 26, 2012, by filing a petition for declaratory and injunctive relief attacking the first lethal-injection protocol the defendants had adopted after the one which another division of this Court required them to submit in *Taylor v. Crawford*[1] and which the United States Court of Appeals for the Eighth Circuit held to be consistent with the Eighth and Fourteenth Amendments.[2]

2. Their original action sought a declaration that the defendants' use of the execution protocol defendant Lombardi issued on

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[1]No. 05-4173-CV-C-FJG, 2006 WL 1779035 (Doc. No. 195) at 5 & 7-9 (Order of June 26, 2006).

[2]487 F.3d 1072 (8th Cir. 2007), *cert. denied*, 553 U.S. 1004 (2008).

May 15, 2012, violated the Ex Post Facto Clauses of Mo. Const. art. I, § 13, and U.S. Const. art. I, § 10; the Supremacy Clause, U.S. Const. art. VI, cl. 2; the Eighth and Fourteenth Amendments to the United States Constitution; Mo. Const. art. I, § 21; and the separation of powers guaranty of Mo. Const. art. II, § 1, and therefore, as well, a permanent injunction against its application.

3. Subsequently, the defendants removed this action to this Court. Doc. No. 1. As to the cruel and unusual punishments count and the ex post facto law count, this Court denied a motion to dismiss. Doc. No. 31.

4. The parties had agreed on a scheduling order, Doc. No. 14, which the Court followed in substantial part, setting the case for trial on a docket beginning October 7, 2013. Doc. No. 28. After the deadline for discovery had closed, the defendants changed the propofol protocol twice, introducing new chemicals in each new protocol. Doc. Nos. 115 & 139. In the most recent protocol, which they announced on October 22, 2013, they ceased for the time being to press the completely novel notion of using propofol, in favor of using compounding-pharmacy pentobarbital. Doc. No. 144. Remaining relatively constant throughout

the four post-*Taylor* protocols was the use of central line access as a default procedure. *E.g.*, ¶ C.1.'s in Doc. No. 1, Exh. A (state-court petition, Exh. 1, Affidavit of Mark J.S. Heath, M.D.) (Heath Affidavit Exhibit 2) (protocol of May 15, 2012), *with* Doc. No. 117-1 (protocol of August 1, 2013) *with* Doc. No. 139-1 (protocol of Sept. 24, 2013); *see also* Doc. 84, Exh. 4 ("Summary of Facts and Opinions of M3"), *and* Doc. No. 3 at 6 n.1 (first motion to dismiss). Although defendant Dormire gave an affidavit on November 15, 2013—the Friday before an execution—that left the decision to use central line access more in the air (Exhibit 7 at 6-7), defendants have not abandoned completely either the option of using central line access or the option of using propofol. The one constant in the widening gyre of changes to these defendants' protocols is that the protocols, and the oath-taking and press releases in lieu of changes in the actual protocols as the Eighth Circuit contemplated to allow meaningful judicial review,[3] do not stay the same.

5. This Court has the authority to issue declaratory judgments and injunctions against state actors when, as here, the plaintiffs show

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[3]*E.g., Taylor v. Crawford*, 487 F.3d 1072, 1080 (8th Cir. 2007), *cert. denied*, 553 U.S. 1004 (2008).

that the state actors' enforcement of a state-law provision (whether in the form of statutes or analogous to the protocol) is in conflict with the United States Constitution.

Jurisdiction and Venue

6. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331, in that it arises under the Constitution of the United States; under 28 U.S.C. § 1343(a)(3), in that it is brought to redress deprivations, under color of state law, of rights, privileges, and immunities secured by the United States Constitution; under 28 U.S.C. § 1343(a)(4), in that it seeks to secure equitable relief under an Act of Congress, *i.e.*, 42 U.S.C. § 1983, which provides a cause of action for the protection of rights, privileges, or immunities secured by the Constitution and laws of the United States; under 28 U.S.C. § 2201(a), in that one purpose of this action is to secure declaratory relief; under 28 U.S.C. § 2202, in that one purpose of this action is to secure permanent injunctive relief; and under 28 U.S.C. § 1367, in that plaintiffs ask the Court to exercise supplemental jurisdiction over their state-law claims.

7. Venue is proper in this federal judicial district under 28 U.S.C. § 1391(b)(1)-(3) in that (1) defendant Lombardi resides in its territorial jurisdiction; (2) defendant Lombardi's decisions regarding the specific means of using lethal injection are made in its territorial jurisdiction, and (3) defendant Lombardi may be found in its territorial jurisdiction.

Parties

8. Plaintiffs are citizens of the United States and residents of the State of Missouri.

9. Plaintiffs are persons within the jurisdiction of this Court.

10. Plaintiffs have been convicted of first degree murder and sentenced to death. The following table sets out the county and date of each plaintiff's sentence. Plaintiffs are listed in reverse alphabetical order.

Name	**County**	**Date of sentence**
David S. Zink	St. Clair County	July 27, 2004
Michael Worthington	St. Charles County	November 4, 1998
John Winfield	St. Louis County	September 18, 1998
Marcellus Williams	St. Louis County	August 27, 2001

Michael A. Taylor	Jackson County	June 17, 1994
Leon Taylor	Jackson County	April 22, 1999
Walter T. Storey	St. Charles County	December 17, 1999
Herbert Smulls	St. Louis County	September 18, 1992
William Rousan	St. Francois County	October 23, 1996
Earl Ringo	Boone County	July 26, 1999
Roderick Nunley	Jackson County	May 10, 1994
Allen L. Nicklasson	St. Louis County	June 28, 1996
John C. Middleton	Adair County/ Callaway County	April 14, 1997/ March 30, 1998
Paul T. Goodwin	St. Louis County	December 2, 1999
Jeffrey R. Ferguson	St. Louis County	December 8, 1995
Kimber Edwards	St. Louis County	June 27, 2002
Andre Cole	St. Louis County	March 9, 2001
Reginald Clemons	City of St. Louis	April 10, 1993
Cecil Clayton	Jasper County	October 27, 1997
Mark Christeson	Vernon County	October 8, 1999
Russell Earl Bucklew	Boone County	May 19, 1997
David M. Barnett	St. Louis County	May 2, 1997

11. Counsel for the State of Missouri have sought execution dates against plaintiffs Zink, Worthington, Winfield, M. Taylor, L. Taylor, Storey, Smulls, Rousan, Ringo, Nunley, Nicklasson, Middleton, Goodwin, Ferguson, Cole, Clemons, Clayton, Christeson, Bucklew, and Barnett.

12. Counsel for the State of Missouri may imminently be anticipated to seek an execution date against plaintiffs Williams and Edwards.

13. The Missouri Supreme Court set an execution date of October 20, 2010, against plaintiff **Nunley**.

14. The United States District Court for the Western District of Missouri stayed plaintiff Nunley's execution on October 18, 2010, pending disposition of his supplemental petition for habeas corpus, which the respondent in that action opposed. Another division of this Court denied plaintiff Nunley's supplemental petition on April 18, 2013, and denied a timely filed Rule 59(e) motion to alter or amend the judgment, or in the alternative, for the issuance of a certificate of appealability on November 6, 2013. Plaintiff Nunley is in the process of appealing the denial.

15. On August 14, 2013, the Missouri Supreme Court set an execution date of October 23, 2013, against plaintiff **Nicklasson**. On October 11, 2013, the Governor announced that the Department of Corrections would not carry out the execution on the date scheduled, and would devise yet another new execution protocol. Exhibit 1. On October 22, 2013, the Missouri Supreme Court vacated its order of August 14 that had set the execution for the following day. In the same press release in which the Governor cancelled the October 23, 2013, execution date, he said: "The Attorney General will immediately request a new execution date for Allen Nicklasson from the Missouri Supreme Court." *Id.*

16. The same day—with no protocol in effect—counsel for the state filed a motion praying the Missouri Supreme Court to set another date against plaintiff Nicklasson "soon after" the one against plaintiff Franklin.

17. On November 8, the Missouri Supreme Court set a new execution date of December 11, 2013, against plaintiff Nicklasson.

18. On August 14, 2013, the Missouri Supreme Court set an execution date of November 20, 2013, against then-plaintiff **Franklin**.

The Governor's October 11 press release did not address the pending date against then-plaintiff Franklin. Exhibit 1. On the same date as the Governor's press release, Mr. Franklin moved the Missouri Supreme Court to stay the pending execution in order to allow him to raise the legality of the yet-undisclosed new protocol. On October 25, 2013, the Missouri Supreme Court summarily overruled the motion.

19. On November 18, 2013, counsel for Mr. Franklin moved this Court for an order that the defendants not execute him with the claims and issues in this case unresolved. The motion attached documents showing recent changes that the defendants had not disclosed by supplementation of their discovery responses, but had used as a sword to attack the pending efforts to obtain judicial relief or had provided to the media. It also included a declaration from one of the plaintiffs' experts showing the flaws and unanswered questions in one such late-disclosed or nearly-undisclosed document from the defendants. Doc. No. 157. At 4:19 p.m. on November 19, the Court stayed the execution of plaintiff Franklin on the basis of one of the several grounds for a stay that the plaintiffs had tendered—defendants' violation of the Eighth

Amendment—expressly reserving judgment on the remainder of the timely-asserted grounds for a stay. *Id.* at 12.

20. At 12:09 a.m., a panel of the United States Court of Appeals for the Eighth Circuit vacated this Court's stay based on the Eighth Amendment. Exhibits 18-19. At 2:28 a.m., the same tribunal denied rehearing en banc, with three judges dissenting and three judges not participating. Exhibit 22. Its summary order did not address the issues this Court's Order of November 19 and the panel order had left unresolved.

21. In consequence, counsel for the plaintiffs filed two pleadings. At 3:41 a.m., they sought a stay from the United States Supreme Court. Exhibits 24-25. At 5:01 a.m., they filed a motion before this Court to renew their application for injunctive relief as to the grounds they had raised in the motion for stay but that this Court had expressly reserved judgment on and that no other court had reached. Exhibit 28 & Doc. No. 167.

22. At 5:18 a.m., the Supreme Court denied the application for stay. Exhibits 29 & 31. At 5:24 a.m., one of the Court-appointed

counsel for the plaintiffs e-mailed counsel for the defendants to remind them of the pendency of Doc. No. 167 before this Court:

> As you know, we have filed a renewed motion for stay of execution, asking the Court to consider the grounds that it declined to consider after finding that Mr. Franklin had sufficiently proven a viable Eighth Amendment claim. I have contacted the emergency number [for] the U.S. District Court, and the clerk with whom I spoke is contacting Judge Laughrey to alert her of our motion. In the meantime, I expect you and your clients to refrain from executing Mr. Franklin while this matter remains pending.[4]

23. At least one of the Assistant Attorneys General representing the defendants has a Blackberry. Exhibit 34.

24. In the face of the electronic notice of filing from the Court and the foregoing e-mail from counsel, the defendants executed plaintiff Franklin at 6:07 a.m. Exhibit 33.

25. On May 18, 2009, the Missouri Supreme Court set an execution date of June 17, 2009, against plaintiff **Clemons**. On June 5, 2009, the United States Court of Appeals for the Eighth Circuit stayed that execution. Mr. Clemons is pursuing habeas corpus relief under Mo. S. Ct. R. 91, which the respondent in that action opposes. This

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[4]Exhibit 32.

matter is pending before the Missouri Supreme Court. *State ex rel. Clemons v. Larkins*, No. SC90197 (Mo. Nov. 4, 2013) (petitioner's brief filed).

26. Defendant **George A. Lombardi** is the Director of the Department of Corrections of the State of Missouri.

27. Defendant Lombardi's office is at 2729 Plaza Drive, Jefferson City, Cole County, Missouri 65109, in Cole County, Missouri.

28. On information and belief, defendant Lombardi works primarily at the Department's central office as aforesaid.

29. Missouri statute specifically authorizes and directs defendant Lombardi to prescribe and direct the means by which the Department of Corrections carries out executions within the statutorily named methods of lethal gas or lethal injection.[5]

30. Plaintiffs sue defendant Lombardi in his official capacity.

31. At all times and in all respects referred to in this complaint, defendant Lombardi acted and will act under color of state law.

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[5]Mo. Rev. Stat. § 546.720.

32. Defendant **David R. Dormire** is the Director of the Division of Adult Institutions of the Department of Corrections of the State of Missouri.

33. Defendant Dormire's office is at 2729 Plaza Drive, Jefferson City, Cole County, Missouri 65109, in Cole County, Missouri.

34. On information and belief, defendant Dormire works primarily at the Department's central office in Cole County as aforesaid.

35. Defendant Dormire is the chief executive officer of the Division of Adult Institutions, and has command-and-control authority over the officials, officers, and employees of the Department directly or indirectly involved in carrying out executions in the State of Missouri (including defendant Russell), and specifically with respect to the implementation of the current execution protocol.

36. Plaintiffs sue defendant Dormire in his official capacity.

37. At all times and in all respects referred to in this complaint, defendant Dormire acted and will act under color of state law.

38. Defendant **Terry Russell** is the Warden of the Eastern Reception Diagnostic & Correctional Center (ERDCC), 2727 Highway

K, Bonne Terre, St. Francois County, Missouri 63628, in St. Francois County, Missouri, where the State of Missouri has been conducting its executions since April 27, 2005.

39. By virtue of his authority over the staff of ERDCC, defendant Russell is responsible for the way in which executions are conducted in Missouri.

40. Plaintiffs sue defendant Russell in his official capacity.

41. At all times and in all respects referred to in this complaint, defendant Russell acted and will act under color of state law.

42. Defendants **John Does 2-40** are officials, officers, employees, agents, and servants (however denominated) of the State of Missouri who, by virtue of their employment or other status (including independent contractors and volunteers under the supervision of the defendants and their designees), participate in the planning of, purchasing and preparation for, carrying out of, and covering up of details about executions in the State of Missouri.

43. Plaintiffs cannot provide the Court the natural names of these individuals because since 2007, a Missouri statute has purported to require that the names be kept secret.[6]

44. Plaintiffs sue John Does 2-40 in their official capacities.

45. Specifically, defendant M3 is an unidentified physician whom the defendants represent to be a board-certified anesthesiologist and who is an independent contractor of the State of Missouri actively participating in the formulation of execution protocols, training of other executioners, other preparation for executions, personal actions in the course of each execution, and covering up of details about executions.

46. Plaintiffs cannot provide the Court the natural name of M3 because neither he nor the other defendants will release it.

47. Plaintiffs sue M3 in his capacity as an independent contractor and agent of the State of Missouri.

48. Defendant M2 is an unidentified licensed practical nurse and who is an independent contractor of the State of Missouri actively participating in training and other preparation for executions, personal

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[6]Mo. Rev. Stat. § 546.270.2-3, as amended by MO. LAWS 2007, H.B. No. 820, § A.

actions in the course of each execution, and covering up of details about executions.

49. Plaintiffs cannot provide the Court the natural name of M2 because neither he nor the other defendants will release it.

50. Plaintiffs sue M2 in his capacity as an independent contractor and agent of the State of Missouri.

51. Defendant M6 is an osteopathic physician who writes a "prescription" for a deadly drug, naming the condemned prisoner as if he or she were the patient of M6. M6's co-defendants have tendered a redacted copy of the contract between M6 and the Missouri Department of Corrections that the latter provided to the plaintiffs as a partial response to a Missouri Sunshine-Law request. Exhibit 13 at 8-9.

52. Plaintiffs cannot provide the Court the natural name of M6 because neither he nor the other defendants will release it.

53. Plaintiffs sue M6 in his capacity as an independent contractor and agent of the State of Missouri.

54. DD1 is a "compounding pharmacy" that the defendants who head, or work for, the Missouri Department of Corrections have

contracted with to provide a substance which the defendants represent to be pentobarbital.

55. Plaintiffs cannot provide the Court the name of defendant DD1 or where it may be found because the other defendants will not identify it.

56. Plaintiffs sue defendant DD1 in its capacity as an independent contractor to the State of Missouri.

57. DD2 is a "laboratory" that has provided DD1 a report, as DD1's contract with its co-defendants specifies (*e.g.*, Exhibit 9 at 9), about a substance which the defendants represent to be pentobarbital.

58. Plaintiffs cannot provide the Court the name of defendant DD2 or where it may be found because the other defendants will not identify it.

59. Plaintiffs sue defendant DD2 in its capacity as an independent contractor or subcontractor and pro tanto agent of the State of Missouri.

60. On information and belief, defendants Does 2-40 (including M3 and M2) may be found at the Eastern Reception Diagnostic and Correctional Center as aforesaid.

61. At all times and in all respects referred to in this complaint, defendants Does 2-40 (including M3, M2, and M6), DD1, and DD2 acted and will act under color of state law.

62. Each and all of the foregoing defendants Lombardi, Dormire, Russell, Does 2-40 (including M3, M2, and M6), DD1 and DD2 at all times relevant to this complaint were acting or are intending to act in their official capacities with respect to all acts and omissions described in this complaint, and were in each instance acting or are intending to act under color of state law.

63. Defendants and each of them intend to act in their respective official capacities and under color of state law to execute the plaintiffs by lethal injection in the manner set forth in this complaint.

Table of Exhibits

1. Press Release from Governor Jay Nixon, October 11, 2013, *State v. Franklin,* Case No. SC79735 (Mo. Oct. 22, 2013), Response Exhibit B

2. Execution Protocol dated October 18, 2013 (disclosed October 22, 2013), Doc. No. 144-1

3. News Release from Missouri Department of Corrections, "Missouri Department of Corrections adopts new one-drug execution protocol," dated October 22, 2013

4. Expert Report of Mark Dershwitz, M.D., *State v. Franklin,* Case No. SC79735 (Mo. Oct. 22, 2013), Response Exhibit C

5. Declaration of Mark J.S. Heath, M.D., executed Nov. 7, 2013

6. Affidavit of Larry D. Sasich, Pharm.D., M.P.H., FASHP, executed Nov. 7, 2013

7. Exhibits to Respondent's Suggestions in Opposition to Motion for Stay of Execution, *State v. Franklin*, No. SC-79735 (Mo. Nov. 18, 2013)

8. Supplemental Declaration of Larry D. Sasich, Pharm.D., M.P.H., FASHP, executed Nov. 15, 2013

9. Defendants' Missouri Sunshine-Law Response to St. Louis Public Broadcasting

10. Defendants' Missouri Sunshine-Law Response to ACLU of Missouri

11. Defendants' Missouri Sunshine-Law Response to Senator Joan Bray

12. Defendants' Missouri Sunshine-Law Response to Plaintiffs Edwards and Worthington (received Nov. 21, 2013)

13. Defendants' Missouri Sunshine-Law Response to Plaintiffs Bucklew and M.A. Taylor (received November 29, 2013)

14. Associated Press Report of President's Signature of Federal Statute Regulating Compounding Pharmacies

15. Execution Warrant Against Joseph Paul Franklin

16. District-Court Order Granting Stay in *Franklin v. Luebbers* on *Ford-Panetti* Grounds

17. E-Mail Transmitting District-Court Order Granting Stay in *Franklin v. Luebbers* on *Ford-Panetti* Grounds

18. Eighth-Circuit Order Granting Motion to Vacate This Court's Order Granting Stay in This Case

19. E-Mail Transmitting Eighth-Circuit Order Vacating Stay in This Case

20. Order Vacating District-Court Order Granting Motion to Vacate Stay in *Franklin v. Luebbers* on *Ford-Panetti* Grounds

21. E-Mail Transmitting Eighth-Circuit Order Granting Motion to Vacate District-Court Order Granting Stay in *Franklin v. Luebbers* on *Ford-Panetti* Grounds

22. Eighth Circuit Order Denying Rehearing of Vacatur of Stay in This Case (in e-mail format showing time)

23. Eighth Circuit Order Denying Rehearing of Vacatur of Stay in *Franklin v. Luebbers* on *Ford-Panetti* Grounds (in e-mail format showing time)

24. Application to United States Supreme Court for Stay of Execution in This Case

25. E-Mail Transmitting Application to United States Supreme Court for Stay of Execution in This Case

26. Application to United States Supreme Court for Stay of Execution in *Franklin v. Luebbers* on *Ford-Panetti* Grounds

27. E-Mail Transmitting Application to United States Supreme Court for Stay of Execution in *Franklin v. Luebbers* on *Ford-Panetti* Grounds

28. Notice of Electronic Filing (showing recipients) of Doc. No. 167 at 5:01 a.m. on November 20, 2013

29. United States Supreme Court Order Denying Stay in This Case

30. United States Supreme Court Order Denying Stay in *Franklin v. Luebbers* on *Ford-Panetti* Grounds

31. E-Mail Transmitting Orders of United States Supreme Court Denying Stays

32. E-Mail from Joseph W. Luby to Opposing Counsel of 5:24 a.m. on November 20, 2013

33. New York Times Article Covering Execution of Joseph Paul Franklin with Pending Motion Before This Court on Grounds for Stay Timely Presented, Reserved by this Court, and Never Reached by Any Court

34. E-Mail from Michael Joseph Spillane, Mo. Bar No. 40704, to Joseph W. Luby on November 26, 2013, at 6:00 p.m., sent from Blackberry

35. "Chronological Sequence of Execution" from defendants' discovery responses in No. 2:09-04095-NKL (W.D. Mo.)

Factual Basis for Claims

64. In order to replace the protocol that the courts have approved for their use in executing the plaintiffs, the defendants first proposed to use propofol, a substance they knew to cause pain on injection in a portion of persons into whom it is injected. Having changed their litigation positions several times about this protocol, on September 24, 2013, they represented to the press (Exhibit 3) without supplementing their discovery responses that they intended to use

another substance (which they represent to be pentobarbital) ***from a compounding pharmacy***, and did not disclose ***which*** specific pharmacy. Exhibit 2. Because the products of compounding pharmacies do not reflect the FDA regulation that patients, physicians, and forensic experts rely on in making judgments about medications, the September 24, 2013, protocol was no more likely to satisfy the Eighth Amendment and its Missouri constitutional analog than the previous three. It could not replace the FDA-approved and -regulated sodium thiopental that the courts found to satisfy the Eighth Amendment in previous lethal-injection litigation in Missouri. Refusal to disclose the compounding pharmacy aggravates the likelihood that the substance to be injected is not pentobarbital at all, or that it is nowhere near the purity, potency, and efficacy that counsel, experts, courts, and the public have relied on in judging previous lethal-injection protocols.

65. Again without supplementing their discovery, the defendants continued to make changes in the way they intended to execute the plaintiffs, which the plaintiffs discovered from defendants' responses to Missouri "Sunshine Law" requests by collateral sources,

including a former state senator (*see* Exhibit 11) who was involved in amending the statute under which the defendants seek to avoid judicial, professional, and public scrutiny of their practices, and by the plaintiffs themselves through their own counsel. Among these changes was the introduction of a medical doctor or osteopath to write a "prescription" for their latest deadly drug as if the condemned plaintiff were his or her patient. Another was the requirement that defendant DD1 have its deadly drug tested by a laboratory, and that DD1 had in fact done so and submitted the results to its codefendants.

66. With a November 20, 2013, execution date against Mr. Franklin looming, the defendants once more changed their stated execution procedure without changing the protocol. On Friday, November 15, they filed a pleading to which they appended an affidavit collateral to their latest protocol, in which a nonphysician—defendant David R. Dormire—represented to the Missouri Supreme Court that whether its executioners would use central line access would depend on unidentified persons' opinions about the plaintiff's "medical condition":

> If the prisoner's medical condition allows, both the primary and secondary lines will be inserted as peripheral lines. The Department will only utilize a central venous line if the prisoner's

medical condition makes placing a peripheral line impracticable.[7]

67. Like the propofol protocols, the October 22, 2013, compounding-pharmacy "pentobarbital" protocol would aggravate the punishment to which the plaintiffs were subject before they filed this action. Its adoption would constitute the exercise of the legislative power by the executive branch. Its application in the near term—as they have done once, and plan to do eight days hence—would deprive the plaintiffs of due process of law and their right of access to the courts. It would do so by the defendants' use of cascading protocols, litigation-driven epicycles to the protocols, and execution dates to foreshorten the notice and opportunity to be heard of the plaintiffs, the health-care professions, and the public. Most particularly, these tactics affect the ability of appointed counsel to muster expert evidence on the scientific and clinical aspects of the grave constitutional issues each of these protocols have raised. Defendants have behaved in an arbitrary manner so as to do all within their power to make it impossible for the plaintiffs to litigate the constitutional issues the defendants keep

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[7]Doc. No. 157, Exhibit 10.

raising for the first time before the plaintiff with the most pressing need to do so is dead at their hands. It reflects unlawful administrative agency action, when the State of Missouri has by statute committed itself to keep administrative action within the law. In an effort to shield their other constitutional violations and the particulars of their behavior from judicial relief, professional discipline, the general effects of evolving standards of decency on which judicial relief is predicated, the defendants have violated the First Amendment and Mo. Const. art. I, §§ 8-9.

Central Line Access

68. Although the defendants' chosen chemical to kill the plaintiffs has changed, one element of their protocols has remained the same: "Medical personnel may insert the primary IV line as a peripheral line or as a central venous line (e.g., femoral, jugular, or subclavian) provided they have appropriate training, education, and experience for that procedure. The secondary IV line is a peripheral line." Exhibit 2, ¶ C.1.

69. Dr. Mark Dershwitz, a physician whom the defendants have sought to endorse as an expert witness out-of-time, has given a

statement which the defendants' privies have filed in the Missouri Supreme Court to the effect that defendant M3 will continue to be the physician who participates directly in Missouri executions under the latest proposed protocol and "will insert the intravenous catheter." Exhibit 4, ¶ 5. *See also* Exhibit 5, ¶ 14 (plaintiff's expert Dr. Mark Heath draws same factual conclusion from record).

70. The new protocol features substantially the same language as previous protocols concerning the use of a central line, and the defendants' own filings have insisted that central line access would be the primary intravenous line. *Compare* the ¶ C.1.'s in Doc. No. 1, Exh. A (state-court petition, Exh. 1, Affidavit of Mark J.S. Heath, M.D.) (Heath Affidavit Exhibit 2) (protocol of May 15, 2012), *with* Doc. No. 117-1 (protocol of August 1, 2013) *with* Doc. No. 139-1 (protocol of Sept. 24, 2013); *see also* Doc. 84, Exh. 4 ("Summary of Facts and Opinions of M3"), *and* Doc. No. 3 at 6 n.1 (first motion to dismiss).

71. Missouri is the only state whose protocol features the routine use of central line access; other states "require that central access is only available if peripheral access has been attempted and determined

to be impossible." Doc. No. 124-2 (declaration Mark J.S. Heath, M.D., of August 18, 2013), ¶ 17.

72. Central line access is "inherently more invasive and painful." *Id.* ¶ 18; Exhibit 5, ¶ 16. It presents widely recognized and painful complications such as suffocation by collapsed lung; perforation or laceration of large blood vessels leading to severe and fatal hemorrhage or suffocation; perforation of the bowel or bladder; and cardiac arrhythmia leading to hemodynamic collapse and death. *Id.* ¶ 18; Exhibit 5, ¶ 16. These foreseeable complications are "inevitable" when "conducted on a large series of patients or prisoners." Exhibit 5, ¶ 16.

73. Especially as the defendants' counsel and physicians expound them, the defendants' proposed change of chemicals is no panacea for the defects of its previous three protocols.

74. On November 15, 2013, the Friday before the Franklin execution set for 12:01 a.m. on Wednesday, November 20, 2013, defendant Dormire purported to back off of the position the physician-executioner M3 had taken in M3's depositions (including his discounting of the negative externalities of central line access in his non-execution practice), on which experts for both sides had relied for

the premise that M3 would use central line access by default. Doc. No. 157, Exhibit 10, ¶ 6. Unless there are more terms which should be in the protocol, but which the defendants are holding back for the next execution eve, M3 is still the person who decides what "medical condition" and "impractical" mean in practice, *i.e.*, he determines what type of intravenous access to use. On November 18, the plaintiffs brought Mr. Dormire's statement to this Court's attention, in light of the fact that the continued use of central line access figured in the question whether the change of deadly drugs rendered this action moot. In its Order of November 19, 2013, the Court denied the defendants motion to dismiss the action as moot notwithstanding the broad swath of discretion that the last-minute Dormire affidavit confers on M3 in light of his attitude toward central line access. Doc. No. 163 at 2-5. In a phone conference on November 26, 2013, with both sides represented, the Court granted leave to amend and further authorized the plaintiffs to alter the amended pleading tendered as an exhibit to their motion for leave to amend. Doc. No. 181.

Pentobarbital

75. Pentobarbital is a short-acting barbiturate.[8] "Barbiturates act by depressing the central nervous system, particularly on certain portions of the brain, though they tend to depress the functioning of all the body's tissues."[9]

76. Pentobarbital's effects depend on the dosage administered: "Barbiturates are capable of producing all levels of CNS [*i.e.*, central nervous system] mood alteration from excitation to mild sedation, to hypnosis, and deep coma. Overdosage can produce death. In high enough therapeutic doses, barbiturates induce anesthesia."[10] "Barbiturates are respiratory depressants. The degree of respiratory depression is dependent upon dose. With hypnotic doses, respiratory depression produced by barbiturates is similar to that which occurs

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[8]ENCYCLOPEDIA BRITANNICA ONLINE, "barbiturate," *http://www.britannica.com/EBchecked/topic/52936/barbiturate* (last visited Oct. 29, 2013).

[9]*Id.*

[10]National Institutes of Health, DailyMed, "NEMBUTAL SODIUM (pentobarbital sodium) injection," *http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=5c380ab0-4386-48b6-80ab-ca594b23bc74* (last visited Oct. 29, 2013).

during physiologic sleep with slight decrease in blood pressure and heart rate."[11]

77. It is a general rule that the effects of a pharmaceutical depend on the dose. In the case of pentobarbital, a tiny dose will cause little or no effect, a very large dose will cause death, and there is a range of outcomes when the dosage falls between these extremes.

78. But the dose is not simply the gross quantity of the substance. Purity or concentration determines whether or not a given quantity of a substance has a given effect.

79. According to the defendants' expert from the *Taylor* litigation, Dr. Mark Dershwitz, the defendant's latest protocol will purportedly work because it will shut down the supply of blood to the condemned person's brain and other vital organs:

> Pentobarbital causes significant effects on the cardiovascular and respiratory systems. Pentobarbital causes a significant decrease in blood pressure by two distinct mechanisms; it produces a direct effect on the heart to decrease its ability to pump, and it dilates blood vessels. Pentobarbital also inhibits the respiratory centers in the central nervous system to cause

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[11] *Id.*

> apnea, the cessation of breathing. The dose of pentobarbital mandated by the Missouri protocol, 5,000 mg, is an enormous overdose compared to the doses that are administered acutely to patients over the same time frame. The inmate will cease to breathe, and his blood pressure will fall significantly, probably to an unmeasurable value. There will therefore be a lack of delivery of oxygen to vital organs such as the brain and heart that will lead to the inmate's death. [Exhibit 4.]

Compounding Pharmacies

80. Previous lethal-injection protocols had included the option of a pharmacist to assist in preparing the chemicals. ¶ A's in Doc. No. 1, Exh. A (state-court petition, Exh. 1, Affidavit of Mark J.S. Heath, M.D.) (Heath Affidavit Exhibit 2) (protocol of May 15, 2012); Doc. No. 117-1 (protocol of August 1, 2013); Doc. No. 139-1 (protocol of Sept. 24, 2013).

81. The latest protocol's definition of the "execution team" sweeps beyond previous ones that had defined the "team" as the people who performed the actions which would occur on an execution night. The current definition includes the verbs "compound" and "supply":

> The execution team consists of department employees and contracted medical personnel including a physician, nurse, and pharmacist. The execution team also consists of anyone selected by the department director who provides direct support for the administration of lethal chemicals, including individuals who prescribe,

> compound, prepare, or otherwise supply the chemicals for use in the lethal injection procedure.

82. Defendants have announced that they will obtain the pentobarbital they intend to use to execute the plaintiffs from a compounding pharmacy: "The department also announced that it has added a compounding pharmacy to its execution team. The compounding pharmacy will be responsible for providing pentobarbital for executions carried out under the new protocol." Exhibit 3 (press release from Department of Corrections dated Oct. 22, 2013).

83. For generations, American health-care providers and patients have relied on the regulation of pharmaceutical manufacturers by the Food & Drug Administration (FDA) under the auspices of the Food, Drug & Cosmetic Act (FDCA), in order to set the standard for identity, purity, potency, and efficacy of prescription medications. Exhibit 6, ¶ 6 (Affidavit of Larry D. Sasich, Pharm.D., M.P.H., FASHP).

84. In the vast majority of situations, the only time our society relies on pharmaceuticals that have ***not*** been produced subject to FDA regulation is when a prescribing physician believes an individual patient requires a customized preparation rather than a commercially-

available product of an FDA-regulated or -approved manufacturer, for example, "medication for a patient who is allergic to an ingredient in a mass-produced product."[12] Exhibit 6, ¶¶ 5-6.

85. Beginning in 1992, the FDA has been concerned that "some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements."[13] It has issued and periodically revised a Compliance Policy Guide (hereinafter "Guide") with the intent of confining pharmacies' compounding activities to the traditional limits rather than allowing them to undertake the functions of pharmaceutical manufacturers subject to FDA regulation as such.[14]

86. In 1997, Congress sought to amend the FDCA to exempt "compounded drugs" from the FDA's standard drug approval requirements, so long as the providers of the compounded drugs abided by several restrictions, including that the prescription be "unsolicited,"

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[12] *Thompson v. Western States Medical Center*, 535 U.S. 357, 360-64 (2002).

[13] *Id.* at 362.

[14] *Id.*

and that the providers did "not advertise or promote the compounding of any particular drug, class of drug, or type of drug." The Court held that the amendment impermissibly regulated commercial expression.[15]

87. Because neither party sought a writ of certiorari on the Ninth Circuit's decision that the advertising provisions of the new statute were nonseverable, the decision left standing a decision that invalidated the amendment in its entirety.[16] As a result, FDA regulation extends only to traditional pharmacy compounding, which is limited to a pharmacist's use of "active and inactive ingredients to meet the needs of an individual patient that cannot be met with an FDA-approved product for medical reasons, according to a legal prescription for an individual patient." Exhibit 6, ¶ 5.

88. The current Guide reflects the Supreme Court's holding that the 1997 legislation was unconstitutional.[17]

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[15]535 U.S. at 366-77.

[16]535 U.S. at 366.

[17]*http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm* (last visited Oct. 29, 2013).

89. For the most part, the Guide continues to defer compounding pharmacy regulation to the states. Cf. Exhibit 6, ¶ 5 (nontraditional compounding-pharmacy practice "regulated if at all only by the states"). At the same time, it notes the FDA's concern with the blurring of the line between the long-established practice of pharmacists' preparing specific medications for specific patients pursuant to a physician's prescription and the abuse of this professional discretion to get around the rules Congress and the FDA have established for the manufacture of pharmaceuticals:

> an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the [FDCA]. Such establishments and their activities are the focus of this guidance. Some "pharmacies" that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug

> manufacturers and wholesalers than with those of retail pharmacies.[18]

90. The FDA does not have the resources to inspect and otherwise regulate compounding pharmacies even with the limits it has set, as a matter of policy, on its role in regulating them.

91. Compounding pharmacies "are generally not subject to the drug approval process and rigorous checks and regulatory procedures required" of pharmaceutical manufacturers. Exhibit 6, ¶ 9.

92. State regulation of compounding pharmacies varies substantially from state to state; but no state regulates compounding pharmacies in a manner that would replicate the FDA's regulation of pharmaceutical manufacturers.

93. State regulation of compounding pharmacies is subject to limitations on resources at least as pronounced as those applying to the FDA's recessive role in regulating them.

94. On November 18, 2013, after voice votes in each chamber, Congress passed—and on November 27, 2013, the President signed—

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[18] *Id.*

H.R. 3204, entitled the Drug Quality and Security Act. *See* Doc. No. 160, 160-1 & 160-2 *and* Exhibit 14 (President signed bill).

95. This action reflects a rare bipartisan consensus at the national level that compounding pharmacies are under-regulated, and their products are not presently suitable for use with the exception of circumstances in which, in the clinical judgment of a physician having regard for the life rather than the death of an actual patient, an FDA-compliant medication would do more harm that good.

96. One of the principal reasons that the products of compounding pharmacies are unreliable as to identity, purity, potency, and efficacy is that there is no telling where they got the precursor chemicals (the "Active Pharmaceutical Ingredients" or API's) from which they purport to "compound" the product they sell as a given substance. Exhibit 6, ¶¶ 16-35. "Ethical chemical manufacturers who adhere to professional Responsible Care principles are unlikely to sell chemicals that may be used in grey market drug production operations[.]" *Id.* ¶ 21. Compounding-pharmacy businesses operating beyond the traditional function of pharmacists to fashion non-FDA medications for individual patients according to their physician's lawful

prescription when FDA-approved pharmaceuticals would be medically-inappropriate are likely to obtain their raw materials from India or China or other sources not registered with or inspected by the FDA. *Id.* ¶ 20. "Chemicals used in compounding are highly suspect, and there is no practical way to verify their quality, constitution or uniformity in limited pharmacy settings." *Id.* ¶ 19. Compounding pharmacies generally do not have the institutional competence to test their own products—let alone the API's they use, to confirm their identity or to rule out the presence of harmful contaminants. *Id.* ¶ 17.

97. Compounding-pharmacy products do not meet the requirements for identity, purity, potency, efficacy, and safety that pharmaceuticals produced under FDA regulation must meet. Exhibit 6, ¶¶ 11-12. In the context of a lethal injection predicated on the use of pentobarbital, the foregoing flaws in the source and the lack of regulation result in at least several causes for substantial risks of serious, unnecessary, and lingering pain and suffering as well as mental anguish:

a. Lack of identity as to the product the label represents the substance to be;

b. "[S]ub- and super-potency," resulting in unanticipated effects such as pulmonary embolism, nausea and vomiting, suffocation and gasping for breath before the hoped-for loss of consciousness, and partial or complete lack of effect;

c. Contamination with dangerous allergens or substances capable of causing immediate anaphylactic reactions;

d. Contamination with bacteria or fungus with immediate excruciating effects, such as "[h]ighly unpredictable, rapidly evolving, and potentially painful and agonizing reactions" before the condemned person is unconscious (assuming it works even to that extent);

e. Incorrect pH (acidity level) resulting in serious pain from the burning sensation on injection analogous to the effect of injecting an unanesthetized condemned person with potassium chloride; and, without limitation,

f. Formation of precipitates, *i.e.*, solid particles, with the foreseeable result of a painful pulmonary embolism in the most serious of cases. [*Id.* ¶¶ 28-35 & 41-46.]

98. Without troubling themselves to include the asserted fact in the protocol, the defendants have represented first to the Missouri Supreme Court and then to this Court that they have obtained a "test" of the substance DD1 holds out as pentobarbital by a "lab", DD2. In his original affidavit, the plaintiffs' pharmacology expert Dr. Sasich explains that after-the-fact testing cannot make up for the lack of raw materials or API's obtained from reputable suppliers. Exhibit 6, ¶¶ 16 & 24.

99. In specific response to the defendants' last-minute revelations of some testing by someone, Dr. Sasich explains further that the American Association for Laboratory Accreditation (A2LA)—the entity purporting to accredit DD2—has qualifications of "unknown" probative value as to analytical testing of compounding-pharmacy products. Having made it his work to monitor the regulation of compounding pharmacies, Dr. Sasich is aware of no governmental entity, federal or state, that recognizes "accreditation" by A2LA as anything but evidence of membership in a mutual admiration society of substandard drug dealers. Exhibit 8, ¶ 1. He points out that DD2's indication of a given concentration level was "not validated." His expertise reinforces logic in pointing out that this admission "erodes confidence in the reported concentration." *Id.* ¶ 3. He points out that the report leaves at least as many questions unanswered as it purports to answer:

A. What is the source of the pentobarbital sodium active pharmaceutical ingredient (API)?

B. Does this pentobarbital sodium API meet USP standards?

C. Was this pentobarbital sodium produced in a Food and Drug Administration facility

meeting Good Manufacturing Practice Guidelines?

D. Was the compounded pentobarbital sodium produced in a facility that would assure that cross-contamination would not occur with drugs that could cause potentially serious allergic reactions?

E. Why was this pentobarbital sodium not tested for adulterants, endotoxins, and sterility?[19]

100. Dr. Sasich concludes by citing the public FDA investigation of "five commercial analytical laboratories [like DD2] for more than 70 safety problems." These were not drawn at random: the same entities run tests like the one the defendants rely on "for about 90 percent of the large compounding pharmacies" in the United States. *Id.* at 2.

101. From these facts Dr. Sasich has formed the expert opinion that the defendants' "report" does virtually nothing to rule out the well-documented threats of sub- or super-potency or other flaws which would result in an excruciating death or a brain-dead prisoner no longer competent to be executed again:

> The documents provided by the Missouri Department of Corrections only indicate that the

[19]Exhibit 8, ¶ 3.

> product that was tested may contain pentobarbital sodium. There is no indication that this product was sterile, free from cross-contamination or other adulterants that could pose a serious risk to the prisoner receiving an injection of this product.[20]

102. Under the defendants' latest protocol, regardless of their incognito status, one would know one fact about any compounding pharmacy or compounding pharmacist that would provide its "execution teammates" with what it represents to be pentobarbital: they do not abide by the norms of the health-care professions with respect to using their skills to assist in killing human beings. These norms do not stop with the Hippocratic Oath's commitment to give no deadly drug and the admonition "First, do no harm." The first Principle of the American Pharmacists Association's Code of Ethics for Pharmacists is that "[a] pharmacist respects the covenantal relationship between the patient and pharmacist", which the Code elaborates to mean that a pharmacist "promises to help individuals achieve optimum benefit from their

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[20] *Id.* at 2.

medications, to be committed to their welfare, and to maintain their trust."[21]

103. There is a causal relationship between a health-care provider's willingness to adhere to professional ethics and the quality of health-care the health-care provider delivers.

104. In all previous lethal injection litigation before this Court—and the bulk of lethal-injection litigation generally—when parties have contested the use of a given substance as a lethal agent or an anesthetic to be used in advance of the lethal agents, the parties have been able to rely on the identity of the substance and the fact that it would be of the identity, purity, potency, and efficacy required by the FDA and reflecting the FDA's supervision of the preparation of the substance. The effects of the administration of a given amount of a given substance were amenable to prediction, without speculation, based on expert opinions working from the known facts about FDA-compliant production.

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[21] *http://www.pharmacist.com/code-ethics* (last visited Nov. 6, 2013).

Nondisclosure of Identities of Compounding Pharmacies

105. In the press release through which the plaintiffs' counsel received much of their "notice" to date about how the defendants plan to carry out their latest protocol, the defendants say, "[t]he department [of corrections] announced that it has added a compounding pharmacy to its execution team." Exhibit 3.

106. The Missouri statute on methods of execution provides that "[t]he director of the department of corrections shall select an execution team which shall consist of those persons who administer lethal gas or lethal chemicals and those persons, such as medical personnel, who provide ***direct support*** for the ***administration*** of lethal gas or lethal chemicals."[22]

107. Defendants appear to construe the foregoing statute to delegate to the Director of the Department of Corrections the power to define the members of the team, and thereafter to make the identity of the "members" the Department designates a state secret: "The identities of members of the execution team, as defined in the execution protocol of the department of corrections, shall be kept confidential.

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[22]Mo. Rev. Stat. § 546.720.2 (emphasis supplied).

Notwithstanding any provision of law to the contrary, any portion of a record that could identify a person as being a current or former member of an execution team shall be privileged and shall not be subject to discovery, subpoena, or other means of legal compulsion for disclosure to any person or entity . . . ."[23]

108. Subsection 4 of the same statute shields members of the "execution team" from disciplinary action, without expressly limiting this immunity to state agencies:

> Notwithstanding any provision of law to the contrary, if a member of the execution team is licensed by a board or department, the licensing board or department shall not censure, reprimand, suspend, revoke, or take any other disciplinary action against the person's license because of his or her participation in a lawful execution. All members of the execution team are entitled to coverage under the state legal expense fund established by section 105.711 for conduct of such execution team member arising out of and performed in connection with his or her official duties on behalf of the state or any agency of the state, provided that moneys in this fund shall not be available for payment of claims under chapter 287.[24]

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[23]*Id.* (emphasis supplied).

[24]Mo. Rev. Stat. ch. 287, in turn, is the workers' compensation statute.

109. Although the latest protocol itself does not use the same language, the press release through which the defendants' counsel chose to apprise the plaintiffs of their actual intentions sweeps more broadly than Mo. Rev. Stat. § 546.720.2 to say that the execution team will include a "compounding pharmacy." In light of the defendants' conduct in this litigation to date, there is no reasonable likelihood that the non-identity of the language in the two documents would mean that the plaintiffs or the public would be allowed to know which compounding pharmacy was the proximate source of the substance.

110. Consequently, if the defendants are allowed to continue with their latest protocol, they will be able to kill the plaintiffs without providing their counsel, their experts, this Court, or any other court the slightest information whatsoever about the provenance of the substance they tender to the courts and the public as pentobarbital. The only assurance the judiciary, the people of Missouri, or the plaintiffs who face execution would have that the actual substance the executioners will use is in fact pentobarbital would be the word of the defendants.

111. The facts previously pleaded about the unreliability of products that are not FDA-compliant (paragraphs 83-104) are

exponentially more compelling when one does not know the track-record of the compounding pharmacy from which the defendants purchase the substance they claim to be pentobarbital, the source from which the compounding pharmacy received the materials it compounds, and the degree to which the compounding pharmacy deviates from the practices the FDA would impose if the compounding pharmacy were a real pharmaceutical company.

112. Within the known range of effects of an unknown effective dose of pentobarbital, there is a zone in which a person will be unconscious but not dead. The "apnea" of which the defendants' putative expert speaks is but a general case of a common medical condition that is usually ***not*** fatal.[25] In a proportion of cases that will be calculated only if this protocol is tried time after time, the condemned person will not breathe at all well, but will just lie on the gurney for a period of time, then recover from the anesthetic effect of

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[25] *Compare* MediLexicon, "apnea," *http://www.medilexicon.com/medicaldictionary.php?t=5507* (last visited Oct. 28, 2013) (defining term as "Absence of breathing") *with* National Institutes of Health, MedLinePlus, "Sleep Apnea," *http://www.nlm.nih.gov/medlineplus/sleepapnea.html* (last visited Oct. 28, 2013).

the dose of nonstandard identity, purity, potency, or efficacy—but not from the brain damage which is a known consequence of the respiratory depression which was supposed to have killed them. The foreseeable consequence of using unregulated pentobarbital from an unknown source is that the condemned person will become incompetent to be re-executed due to the defendants' choice of a protocol. Exhibit 5, ¶ 9 (Declaration of Mark J.S. Heath, M.D.).

113. By any measure, such an execution would come within either side's definition of risk or harm.

114. With neither FDA regulation nor the ability to assess the competence of the compounding pharmacy in question, one does not even know what substance the defendants will administer to kill a given plaintiff on the first attempt or any second or subsequent attempt.

115. This is one reason why the defendants' promised death check (Exhibit 2, ¶ E.4-5) does not eliminate the foregoing problem. If the condemned person is not dead when he or she was supposed to have been, then that means something is wrong with the product which was first administered. Either it is not in fact pentobarbital, or the purity,

potency, and efficacy of the batch the defendants have used is (as one would expect) sub-par. Administering more of the same substance that had failed before would not have a scientific basis, because if the first dose had worked, one would not need the second. One has no way of knowing whether the effective dose of the second or subsequent batch is even lower than that of a previous one. Exhibit 5, ¶ 9.

116. Despite one's inability to learn which compounding pharmacy (or compounding pharmacist) is on the "team," one knows that they pick and choose which norms of the health-care professions they will follow. *Cf.* para. 102, *supra.*

Increase in Quantum of Harm over Previously-Approved Protocol

117. In *Taylor v. Crawford*, another division of this Court required the defendants' predecessors in office to issue a written protocol.[26]

118. While the federal district court's order in *Taylor* was on appeal, the defendants' predecessors in office terminated the services of a surgeon they had employed to assist in executions even after plaintiff

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[26]*Taylor v. Crawford*, No. 05-4173-CV-C-FJG, 2006 WL 1779035 (Doc. No. 195) at 5 & 7-9 (Order of June 26, 2006).

Michael Anthony Taylor demonstrated that this defendant, John Doe 1, admitted to being dyslexic and to getting dosages mixed up—in some instances giving less than the amount of sodium thiopental the unwritten protocol required in order to anesthetize the condemned person before injecting him with the other two lethal chemicals.

119. Eventually, after the changes that the district court had ordered after an evidentiary hearing in Mr. Taylor's case, the federal courts rejected remaining issues with the three-chemical sequence and with the Missouri defendants' practices for implementing it at the time.[27]

120. The Eighth Circuit held that the protocol the defendants adopted under this Court's Order in *Taylor* met the constitutional standard for lethal injection that the Supreme Court had set in *Baze v. Rees*.[28]

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[27]*Clemons v. Crawford*, 585 F.3d 1119 (8th Cir. 2009), *cert. denied*, 130 S.Ct. 3507 (2010); *Taylor v. Crawford*, 487 F.3d 1072 (8th Cir. 2007), *cert. denied*, 553 U.S. 1004 (2008).

[28]553 U.S. 35 (2008). *See Clemons v. Crawford*, 585 F.3d at 1126-28; *Taylor v. Crawford*, 487 F.3d at 1085.

121. At every stage, the *Taylor* decision presumed the use of substances produced consistently with the FDCA, including FDA regulation and supervision; counsel, experts, and courts alike were able to predict the effects of the substances involved based on this presumption.

122. In the instant case, because compounding pharmacies are not regulated by the FDA and do not have the institutional competence of the pharmaceutical manufacturers that are (Exhibit 6, ¶ 9), the names in protocols mean, at most, the names printed, typed, or scrawled on the bottles.

123. In 2012, the defendants in *Ringo v. Lombardi* represented to the Eighth Circuit that their stock of sodium thiopental had gone out-of-date, and they were unable to obtain more because the manufacturer would not sell it to them for use in executions. The Eighth Circuit accepted this premise, and held the case moot.[29]

124. Under the *Taylor* decision, the initial injection of FDA-compliant sodium thiopental would render the condemned person

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[29]677 F.3d 793 (8th Cir. 2012).

unconscious and therefore unable to experience suffocation from the second substance, FDA-compliant pancuronium bromide, and the burning and heart attack caused by the third, FDA-compliant potassium chloride.[30]

125. Removal of FDA regulation and supervision from the substance the defendants propose to use in their latest protocol means that the likelihood of pain and suffering is greater than it was under the protocol the Eighth Circuit approved in *Taylor*.

126. Like his three previous attempts to change the *Taylor*-approved protocol, defendant Lombardi's change of the protocol occurred after the offenses for which the plaintiffs were sentenced to death.

Exercise of Legislative Power by Executive Branch

127. As set forth in para. 107, *supra*, Mo. Rev. Stat. § 546.720.2 provides: "The identities of members of the execution team, ***as defined in the execution protocol of the department of corrections***, shall be kept confidential. Notwithstanding any provision of law to the contrary, any portion of a record that could identify a person as being a

[30]487 F.3d at 1082-85.

current or former member of an execution team shall be privileged and shall not be subject to discovery, subpoena, or other means of legal compulsion for disclosure to any person or entity . . . ." *Id.* (emphasis supplied).

128. In the press release announcing how the defendants intend to obtain compounding-pharmacy pentobarbital, they say that the Department of Corrections "has added a compounding pharmacy to its execution team." Exhibit 3.

129. Whereas the core sentence in the statute saying what its protection means in practice refers to "person," and the provisions immunizing such persons from professional regulation uses the term expression "his or her" as a relative pronoun phrase, the language on which the defendants rely in making a company part of the "team" uses the word "member."

130. Since the *Taylor* order that first required a written execution protocol in this state, the only written protocols have limited the "team" to individuals such as medical personnel and nonmedical staff who would be present in person at the execution:

1. The execution team consists of contracted medical personnel and department employees.

2. A physician, nurse, or pharmacist prepares the chemicals used during the lethal injection.

3. A physician, nurse, or emergency medical technician (EMT-intermediate or EMT-paramedic) inserts intravenous lines, monitors the prisoner, and supervises the injection of lethal chemicals by nonmedical members of the execution team.

4. Two department employees inject the chemicals into the prisoner.[31]

131. The past practice of the Department of Corrections reflects that the original understanding and the plain meaning of the statute is to cover individuals present at the execution.

132. Regardless of what the General Assembly intended, the defendants now have a litigation incentive to make the company a member of the "team" in order for it to be free from scrutiny as to its track-record for regulatory violations and absence of extraordinary

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[31]¶A's in Doc. No. 1, Exh. A (state-court petition, Exh. 1, Affidavit of Mark J.S. Heath, M.D.) (Heath Affidavit Exhibit 2) (protocol of May 15, 2012); Doc. No. 117-1 (protocol of August 1, 2013); Doc. No. 139-1 (protocol of Sept. 24, 2013). The same language appears in the protocol at issue in *Ringo v. Lombardi*, No. 2:09-04095-NKL (W.D. Mo.), *e.g.*, Doc. No. 155, Exh. 1.

indicia of reliability that might conceivably put it in the FDA-regulated category (a proposition the plaintiffs do not suggest could be established in any event).

133. Making the compounding pharmacy or compounding pharmacist a member of the "team" is also necessary to immunize them from the enforcement of professional norms by professional associations and regulators, by other compounding pharmacies, by health-care professionals who would otherwise write prescriptions for them to fill, by suppliers who would otherwise sell them raw materials, and by customers who do not choose to trade with pharmacies or pharmacists that use their professional skills to facilitate executions.

134. The fact that a litigation incentive has arisen subsequent to the passage of the bill does not change the words of the resulting statute.

135. Mo. Rev. Stat. § 546.720.1-2 does not give defendant Lombardi a general authority to make whomever or whatever he chooses a "member" of the "execution team" in the way that it gives him the responsibility of providing a "suitable and efficient room or place, enclosed from public view" and the "necessary appliances" for carrying

out a method of execution from the two-method list the statute provides. It provides that he "shall select an execution team which shall consist of those persons who administer lethal gas or lethal chemicals and those persons, such as medical personnel, who provide ***direct support*** for the ***administration*** of lethal gas or lethal chemicals." (Emphases supplied.)

136. The statute's use of the noun "persons", the example of "medical personnel", the adjective "direct" modifying "support", and the noun "administration," indicate that the General Assembly intended his discretion to extend only to natural persons who are personally present and active in the execution itself.

137. Even if one were to discount the defendants' representations in Exhibit 3 that they will use a compounding pharmacy, a compounding pharmacist would not need to be, and in fact could not be, present on an execution night. Compounding an injectable drug such as pentobarbital requires a separate facility designed for that specific purpose. See 20 C.S.R. § 2220-2.200(1)(H) (defining injectables as "compounded sterile medications"); 20 C.S.R. § 2220-2.200(5) (governing "facilities and equipment" for sterile compounded medications).

138. The compounder therefore does not provide "direct" support as do statutorily-encompassed "medical personnel" such as anesthesiologist M3, who oversees the execution itself and supervises nonmedical personnel as they inject the drug by pushing the syringes. Exhibit 2, ¶ E1.

139. The General Assembly intended to provide anonymity and professional-disciplinary immunity to executioners and "those persons, such as medical personnel, who provide direct support for the administration of lethal gas or lethal chemicals." Mo. Rev. Stat.§ 546.720.2.

140. Whatever or whoever makes the substance does not administer it or assist someone else in doing so. As a matter of Missouri law, the names of vendors, suppliers, and contracts of state agencies are presumptively matters of public record. *See* Mo. Rev. Stat. § 610.010.6 (Sunshine Law definition of "public record").

141. Unlike the details of the protocol per se, suppressing the identities of participants in a process does not call for specialized, scientific knowledge beyond the competence of a legislative body.

142. Because the General Assembly makes the laws concerning regulation of professions and occupations, and defendant Lombardi runs prisons, he is not in a superior position to say who should be anonymous and who should not be in relation to the board or department the General Assembly has charged with regulating them.

143. By purporting to make a compounding pharmacy and an osteopath who simply writes prescriptions rather than attending the execution members of the team, defendant Lombardi has changed the terms of the statute as if he were the General Assembly.

144. In the alternative, if the words of the statute are plastic enough that this is not an involuntary act from the legislature's point of view, but within its intent, then the General Assembly has conferred its own power on an appointed executive official.

145. Regardless whether the legislature or the executive actor is dominant in effecting this change to composition of the "execution team" for secrecy purposes, the protocol attempting to do so is an exercise of the legislative power by an unelected official or officer of the executive branch.

Denial of Notice and Opportunity to Be Heard

146. The protocol that is the subject of this amended complaint is the fourth since May 2012.

147. Defendants covertly adopted the first propofol protocol on May 15, 2012.

148. Defendants did not give notice to plaintiffs of the first propofol protocol until May 17, 2012.

149. Plaintiffs' first notice of this protocol was a set of ex parte contacts with the bulk of the plaintiffs, all of whom were then and are now represented by counsel, either before or simultaneously with the filing of nineteen motions in the Missouri Supreme Court to set execution dates.

150. Defendants resisted all efforts by the plaintiffs and their counsel to see that execution dates were set under the first propofol protocol only after the courts had been able to decide on its constitutionality.

151. Defendants adopted the second propofol protocol on August 1, 2013.

152. Plaintiffs and their counsel first learned of the second propofol protocol on August 2, 2013.

153. Defendants' counsel, ex parte, provided a copy of the second propofol protocol and the affidavit of defendant Dormire containing terms appurtenant it to the Missouri Supreme Court on August 2, 2012.

154. On August 14, 2013, the Missouri Supreme Court set execution dates against plaintiff Nicklasson and then-plaintiff Franklin, as October 23, 2013, and November 20, 2013, respectively.

155. On September 24, 2013, less than a month before the scheduled execution of plaintiff Nicklasson, defendants issued the third propofol protocol. Doc. No. 139, Exh. 1.

156. In a press release on October 11, 2013, the Governor announced that the state had chosen not to proceed with the use propofol, but that it would prepare yet another protocol. He cancelled the October 23 execution date against plaintiff Nicklasson on October 11 (Exhibit 1), and the Missouri Supreme Court vacated it on October 22. The November 20 execution date against Mr. Franklin remained standing, and a new execution date of December 11 has now been set against plaintiff Nicklasson.

157. Defendants and their predecessors in office perform Missouri executions at 12:01 a.m., with the effect that absent pending court action drawing the execution in question at the latter time, the last day on which counsel or the courts could take any action on Mr. Franklin's case was November 19 and on plaintiff Nicklasson's case would be December 10.

158. Neither in the foregoing press release (Exhibit 1) nor in any other public statement did Governor Nixon commit that the Department of Corrections would never use propofol as a killing agent. The current protocol does not include propofol. It is impossible to ascertain at this time how propofol might be used by the Department of Corrections in a future execution protocol. Plaintiffs' failure to include averments and counts in this amended complaint concerning the use of propofol is not intended as an admission that any of defendants' propofol protocols were constitutional.

159. On October 18, 2013, the defendants adopted the protocol that is at issue (for the time being) in this case.

160. Defendants announced this protocol to the plaintiffs and their counsel on October 22, 2013.

161. When counsel for Mr. Franklin sought an order from the Missouri Supreme Court vacating the outstanding execution date of November 20 against him, the defendants' privies in the Attorney General's Office opposed the motion.

162. On October 25, 2013, the Missouri Supreme Court summarily overruled Mr. Franklin's motion to vacate its execution date of only one month from the defendants' announcement of their current post-*Taylor* execution protocol.

163. Defendants' conduct in this matter is calculated, or is so likely as to be attributable to them as if it were calculated, to prevent the plaintiffs from ascertaining the facts about each of the past protocols as well as the present protocol in such a manner as to determine whether any of the protocols is consistent with the constitutional guaranties against cruel and unusual punishments and with the other provisions of law set forth in this complaint.

164. Defendants' actions are calculated and likely to force the plaintiffs to litigate the claims and issues resulting from their change of protocols—including their claim to a day in court—under the harsher

standard for issuance of a stay of execution rather than under the legal standard that would apply but for the defendants' conduct.

165. Each and every plaintiff is indigent, confined in a maximum security prison, and represented by appointed counsel.

166. Forcing counsel to litigate these technical issues—requiring expert consultations and discovery with execution dates looming as imminently as in this case creates a burdensome strain that places the plaintiffs at an artificial disadvantage created by the defendants.

167. For example, in its one-page order vacating this Court's stay of execution as to Mr. Franklin, the Eighth Circuit cited the lack of evidence to support the plaintiff's assertion that his execution under the most recent protocol would constitute cruel and unusual punishment. Exhibit18. That lack of evidence was largely due to the plaintiffs' inability to develop the facts in the face of the defendants' repeated changes of circumstances.

168. Plaintiffs have a liberty interest under the Due Process Clause of the Fourteenth Amendment in not being executed by the state in violation of the Cruel & Unusual Punishments Clause of the Eighth Amendment.

169. Plaintiffs have a liberty interest under the First Amendment and the Due Process Clause of the Fourteenth Amendment in access to the courts.

170. At the time of each of the last three adoptions of post-*Taylor* execution protocols, the bulk of the plaintiffs, including plaintiffs Nicklasson and Franklin, were parties to this litigation, which the defendants removed to this Court.

171. Defendants' conduct would deprive the plaintiffs of their liberty by means of denying them a day in federal court on their claims that the protocol, and the means of its adoption and enforcement, violate the Constitution and statutes of both Missouri and the United States.

172. Allowing the defendants to hide the ball until after the Missouri Supreme Court has set execution dates renders 42 U.S.C. § 1983 a dead letter, whether a condemned person's action was brought in state or federal court.

173. De facto deprivation of a federal-court remedy for the plaintiffs' underlying constitutional violations would violate Due Process Clause of the Fifth Amendment.

174. Insofar as Mo. Const. art. I, § 10, is to be construed coterminously with the Due Process Clauses of the Fifth and Fourteenth Amendments, denial of a day in court on the merits of the petitioners' claims of cruel and unusual punishments and the application of an ex post facto law would violate the state guaranty of due process as well.

175. To the extent that Mo. Const. art. I, §§ 8-9, are to be construed coterminously with corresponding guaranties of the First Amendment, denial of a day in court on the merits of the petitioners' claims of cruel and unusual punishments and the application of an ex post facto law would violate the state guaranty of freedom of expression as well.

Defendants' Conduct in the Execution of Joseph Paul Franklin

176. On August 14, 2013, the Missouri Supreme Court issued a warrant for the execution of Joseph Paul Franklin to occur on November 20, 2013. Exhibit 15. Pursuant to Missouri law, the execution could properly be carried out any time before 12:00 a.m. on November 21. It is the practice of the state defendants and their

predecessors in office to carry out executions at 12:01 a.m. on the date the Missouri Supreme Court has set.

177. Governor Nixon's press release of October 11, 2013 (Exhibit 1), cancelled the October 23 date against plaintiff Nicklasson did not address the pending date against Mr. Franklin, then of course a plaintiff before this Court. On the same date as the Governor's press release, Mr. Franklin moved the Missouri Supreme Court to stay the pending date of November 20, 2013, in order to allow him to assess the legality of the yet-undisclosed new protocol. On October 25, 2013, the Missouri Supreme Court overruled the motion.

178. On November 18, 2013, Mr. Franklin moved this Court for an order staying his execution. The motion attached documents showing recent changes that the defendants had not disclosed by supplementation of their discovery responses in the instant case before this Court. It also included a supplemental declaration from Dr. Sasich showing the flaws and unanswered questions in on such late-disclosed or nearly-undisclosed document from the defendants. Doc. No. 157.

179. At 4:19 p.m. on November 19, 2013, this Court stayed Mr. Franklin's execution. Doc. No. 163. Mr. Franklin had sought the stay

on four grounds; this Court granted relief on one ground—the violation of the Eighth Amendment to the United States Constitution—and ***expressly*** refrained from reaching the remaining grounds:

> Because the Court finds that the stay of execution must be granted on the grounds that Plaintiffs have shown a substantial likelihood of success on the merits of their Eighth Amendment claim, the Court declines to discuss Plaintiff's other arguments on the merits at this time.[32]

180. At 5:40 p.m., a division of the United States District Court for the Eastern District of Missouri stayed Mr. Franklin's execution, on the basis of his claim that he was incompetent to be executed. Exhibits 16-17. Defendants appealed both orders to the United States Eighth Circuit Court of Appeals. In orders issued by e-mail at 12:09 and 12:18 a.m. on November 20, 2013, that court vacated both stays of execution. Exhibits 18-21.

181. Thereafter, the Eighth Circuit denied Mr. Franklin's motions for rehearing and for rehearing en banc, over three dissenting votes, with three additional judges not participating in the decision. Exhibits 22-23.

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[32]Doc. No. 157 at 12.

182. At 3:40 a.m. on November 20, 2013, counsel for Mr. Franklin then filed in the United States Supreme Court a motion for stay. Exhibits 24-25.

183. At approximately 5:01 a.m. on November 20, 2013, while the United States Supreme Court proceedings were still pending, counsel for Mr. Franklin filed in this cause a renewed motion for stay on the basis of the grounds this Court had reserved ruling on in the Order it had issued at 4:19 p.m. the previous day. Doc. No. 167. Opposing counsel received notice of this filing through the Court's electronic filing system at that time. Exhibit 28.

184. Joseph W. Luby, counsel for Mr. Franklin, called the emergency number for the clerk of this Court at approximately 5:10 a.m. to insure that the Court was alerted to the filing.

185. At 5:18 a.m., counsel for Mr. Franklin and the defendants received notice, via e-mail, that the United States Supreme Court had denied the motion for stay. Exhibits 29-31.

186. At approximately 5:24 a.m., November 20, 2013, Mr. Luby sent an e-mail to Susan D. Boresi and Michael J. Spillane, counsel for

defendants, Exhibit 32, reminding them of the filing and stating his expectation that no execution would occur while it was pending:

> As you know, we have filed a renewed motion for stay of execution, asking the Court to consider the grounds that it declined to consider after finding that Mr. Franklin had sufficiently proven a viable Eighth Amendment claim. I have contacted the emergency number [for] the U.S. District Court, and the clerk with whom I spoke is contacting Judge Laughrey to alert her of our motion. In the meantime, I expect you and your clients to refrain from executing Mr. Franklin while this matter remains pending.

187. Mr. Luby never received any electronic notice that might have indicated that his email to defendants' counsel was not successfully delivered. However, he received no response to this e-mail.

188. Despite the electronic notice of filing from this Court and the foregoing e-mail from appointed counsel, the defendants injected Mr. Franklin with some substance at 6:07 a.m. and pronounced him dead at 6:17 a.m. Exhibit 33.

189. At that time, the motion that the plaintiffs had filed in this Court (Doc. No. 167) remained pending.

190. On November 20, 2013, after the defendants had executed Mr. Franklin, this Court denied his motion for stay as moot. Doc. No. 170.

191. It is the written policy of the Missouri Department of Corrections that the prisoner will not be escorted from the holding cell to the execution chamber while there is pending legal activity to halt the execution process.

192. In the written procedure that the defendants and their predecessors in office provided to the plaintiffs in *Ringo v. Lombardi*, No. 2:09-CV-04095-NKL, they set forth the state-created protection for the condemned person requiring an absence of legal impediments for an execution to proceed:

> at 1200 a.m., the Director of the Department of Corrections asks the Attorney General, "Are there any legal impediments or reasons why the lawful execution of (Inmate Name) should not proceed?"[33]

193. At all times when defendants took Mr. Franklin from the holding cell, established IV lines and then executed him via lethal

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[33]Exhibit 35 at 4.

injection, there was legal activity in progress to prevent the execution—the renewed motion for stay that was pending in this Court.

194. Defendants had notice of this legal impediment in at least two ways: (a) by automatic notice sent to defendants' counsel via this Court's ECF filing system at the time Mr. Franklin's counsel filed the renewed motion for stay; and (b) by the e-mail from Mr. Franklin's counsel to defendants' counsel. Exhibits 28 & 32.

195. Accordingly, at all times when defendants took these actions that explicitly deviated from the written execution protocol, defendants ***knew*** that their actions were in violation of the written execution protocol.

196. Equal protection under the law requires "minimal procedural safeguards" providing at least some assurance that the rudimentary requirements of equal treatment and fundamental fairness are satisfied.

197. The Equal Protection Clause's requirements are important here, where the United States Supreme Court has clearly emphasized the necessity of procedural safeguards in a state's lethal injection

execution policy, especially including the written protocol, to ensure against Eighth Amendment and Fourteenth Amendment violations.

198. Plaintiffs have an interest protected by the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution and by Mo. Const. art I, §§2 and 10, in having the State of Missouri follow its announced policies and protocol in their executions.

199. In their deviations or their variations from their execution policy and written execution protocol, defendants are violating the Equal Protection Clause's guarantee of equal treatment for similarly situated persons.

200. On information and belief, the individual or pattern of deviations or variations from defendants' execution policy and written execution protocol exhibited by many of the actors involved, intentionally or recklessly, combined with their wholly subjective, discretionary understanding and application of the execution policy and written execution protocol, along with substantial evidence of incompetence or inability to perform in the execution context

cumulatively point to an unacceptable risk of violating the plaintiffs' rights.

201. Defendants' execution policy and written execution protocol, including their wholly discretionary approach thereto, violates the plaintiffs' rights to equal protection under the law as guaranteed by the Fourteenth Amendment.

202. Plaintiffs are each similarly situated to other condemned prisoners to whom the defendants will apply their execution protocol.

203. Defendants' willful violation of execution policy violated Mr. Franklin's right to due process and equal protection of the laws in a manner that threatens the repetition of the same against every surviving plaintiff.

204. Defendants' actions administering their execution policy and written execution protocol show a pattern of deviations or variations from the execution policy or written execution protocol, intentionally, recklessly or arbitrarily, such that the safeguards allegedly contained in the defendants' execution policy and written execution protocol are applied to a particular inmate arbitrarily and disparately, and that

such deviations or variations are arbitrary and irrational, or not necessary to achieve a compelling governmental interest.

205. This denies the plaintiffs the guarantee that they will receive the full panoply of procedural safeguards in the written protocol, including their right to access to the courts.

206. Thus, the defendants' pattern of deviations or variations from their execution policy and written execution protocol results in each condemned inmate being treated differently and such disparate treatment severely burdens the fundamental rights of the plaintiffs.

207. Defendants' disparate treatment arising from their individual or pattern of deviations or variations from their execution policy and written execution protocol are not necessary to achieve any compelling governmental interest, nor are they the least restrictive means to achieve any compelling governmental interests.

208. By arbitrarily or inconsistently following, deviating or varying from the procedural safeguards in the defendant's execution policy and written execution protocol, and without any justification related to any specific condemned inmate or to any compelling governmental interest, the defendants are arbitrarily denying the

fundamental rights of the plaintiffs under the First, Sixth, Eighth, Ninth, and Fourteenth Amendments.

209. Each plaintiff has been or will be singled out arbitrarily and irrationally as a "class of one" who will not be afforded equal protection as represented by the procedural safeguards in the defendants' written execution protocol, when such written safeguards are disregarded, ignored, deemed discretionary or advisory only, or otherwise not followed, intentionally or otherwise, during administration of the execution policy.

210. Defendants' individual or pattern of deviations or variations from their execution policy and written execution protocol arbitrarily and irrationally treat similarly situated inmates differently.

211. Defendants' disparate treatment arising from their individual or pattern of deviations or variations from their execution policy and written execution protocol are arbitrary, they are irrational, they further no legitimate state interests, or there is no relationship between the deviations or variations and any legitimate state interest.

212. Any justifications that defendants might offer for their deviations or variations are without any rational relationship to a particular condemned inmate.

213. Any justifications that defendants might offer for their deviations or variations amount to claims of administrative convenience, or claims of simply ensuring that an execution is carried out at all costs, neither of which is a legitimate governmental interest.

214. Defendants' execution policy and written execution protocol are considered binding state law, and thus defendants violate state law when they fail to abide by the explicit mandates of their execution policy or written execution protocol.

215. State actions that are clearly contrary to law are irrational, and therefore the defendants' deviations or variations are irrational.

216. Plaintiffs are dissimilar from each other only in immaterial respects as it relates to the defendants' pattern of deviations or variations, or the defendants' deviations or variations are not rationally founded on differences that are real and not illusory.

217. Defendants' pattern of deviations or variations is irrational because it is arbitrary and capricious; it is a pattern of random deviations or variations that changes from execution to execution.

218. In all the foregoing ways, the defendants violate the plaintiffs' rights to equal protection of the laws and to due process of law, in violation of the Fourteenth Amendment to the United States Constitution and Mo. Const. art. I, §§ 2 & 10.

Administrative Action in Violation of Constitutional, Statutory, Rule-Based, and Regulatory Authority and Otherwise Unlawful and Amenable to Judicial Review

219. As set forth in para. 107, *supra*, Mo. Rev. Stat. § 546.720.2 provides that the identities of members of the "execution team"—"as defined in the execution protocol of the department of corrections"—shall not be disclosed even in response to legal process.

220. As the facts set forth in paras. 105-142, *supra*, demonstrate, Mo. Rev. Stat. § 546.720.1-2 does not give defendant Lombardi a general authority to make whatever he chooses—such as his dog or cat, his favorite horse, or the People's Republic of China—a "member" of the "execution team".

221. The statute does provide that defendant Lombardi "shall select an execution team which shall consist of those persons who administer lethal gas or lethal chemicals and those persons, such as medical personnel, who provide ***direct support*** for the administration of lethal gas or lethal chemicals." (Emphasis supplied.)

222. Because the General Assembly makes the laws concerning regulation of professions and occupations, and defendant Lombardi runs prisons, he is not in a superior position to say who should, or should not be, anonymous in relation to the board or department the General Assembly has charged with regulating them.

223. By purporting to make a compounding pharmacy or a compounding pharmacist, and a prescribing medical doctor or osteopath, a member of the team, defendant Lombardi has changed the terms of the statute as if he were the General Assembly.

224. Missouri law holds out a remedy for executive action beyond the bounds of the law. Mo. Rev. Stat. § 536.140 provides for judicial review of administrative agency action that

> (1) Is in violation of constitutional provisions;
>
> (2) Is in excess of the statutory authority or jurisdiction of the agency . . .

(4) Is, for any other reason, unauthorized by law;

(5) Is made upon unlawful procedure or without a fair trial;

(6) Is arbitrary, capricious or unreasonable; [or]

(7) Involves an abuse of discretion.

225. Defendants have removed the plaintiffs' action, which seeks relief on both federal-law and state-law grounds from the defendants' cascading execution protocols, from state court to federal court. Doc. No. 1.

226. Defendant Lombardi's adoption of the latest protocol is amenable to relief under several points in the foregoing statute.

227. Plaintiffs have pleaded as a separate count that this action violates the state constitutional guaranty of separation of powers because it is an exercise of the legislative power by an executive official. In addition to being remediable in this section 1983 action, it is amenable to relief under the express terms of section 536.140.

228. If defendant Lombardi's action is "in excess of the statutory authority or jurisdiction of the agency" or "for any other reason, unauthorized by law", and then it is remediable under points (2) and (4) in subsection 2 of section 536.140.

229. Defining "execution team" to include a company or corporation (or, if one discounts Exhibit 3, an individual compounding pharmacist operating off-site and before the execution) is for the purpose of avoiding discovery in the courts, professional regulatory action or ethics enforcement by agencies, associations, cognate professionals, and consumers—all in order to facilitate constitutional violations by precluding the plaintiffs and their counsel and experts from knowing what the source of the substance is so that they can evaluate it.

230. Defendants are under an ongoing legal duty to supplement discovery in this very action, yet instead of notifying the plaintiffs' counsel about their recently-announced protocol and implementing press release before they tendered them to the media, they concealed them in order to spring them on appointed counsel and thereby avoid a fair trial on their latest protocol.

231. Therefore, the action was taken through an "unlawful procedure or without a fair trial" and is arbitrary, capricious, unreasonable, and an abuse of discretion. The chosen action is also arbitrary and capricious because is it unreasonable for the Department

of Corrections to carry out executions using compounding-pharmacy drugs, which subject the plaintiffs to an unnecessary and substantial risk of severe pain during their executions.

232. It is therefore remediable under the remainder of subdivision 2 of section 536.140.

233. In addition to the foregoing constitutional, federal-rule, and legal-ethical grounds, the protocol violates at least three portions of the Missouri state regulations on compounding pharmacies.

234. Title 20 C.S.R. § 2220-2.400(9) provides that "[c]ompounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products is prohibited." *See* Exhibit 6, ¶ 5.

235. Title 20 C.S.R. Sec. 2220-2.400(10) provides that "[a]ny alteration, change or modification to the contents of a commercially manufactured over-the-counter product shall require a prescription or prescription drug order from an authorized prescriber. The compounding of any drug product to be sold without a prescription is prohibited."

236. Title 20 C.S.R. Sec. 2220-2.400(12) provides that "[p]harmacists shall not offer compounded drug products to other pharmacies, practitioners or commercial entities for subsequent resale or administration, except in the course of professional practice for a prescriber to administer to an individual patient by prescription." *Cf.* Exhibit 6, ¶ 5, 6 & 15.

237. Defendants represent the substance they intend to obtain from a compounding pharmacy to be pentobarbital.

238. A Missouri agency's duly promulgated "rules," including those promulgated by the Board of Pharmacy,[34] carry the force and effect of law.[35] Such rules include those enacted by the Board of Pharmacy under its statutory authority.[36] Plaintiffs have a private right of action to enforce such regulations under the Missouri Administrative Procedure Act, which allows for judicial review of agency action that exceeds the agency's "statutory authority" or is

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[34]*See* Mo Rev. Stat. §§ 338.010, 338.140, 338.240, 338.280.

[35]*Page Western, Inc. v. Community Fire Protection Dist.*, 636 S.W.2d 65, 68 (Mo. banc 1982).

[36]*See* Mo Rev. Stat. §§ 338.010, 338.140, 338.240, 338.280.

otherwise "unauthorized by law."[37] Plaintiffs fall squarely within the zone of interests of the regulatory framework, which serves to protect the public health and safety, including the persons who actually receive pharmaceuticals. The Department of Corrections seeks to administer an illegally- and unsoundly-compounded pharmaceutical simply because it says it cannot purchase the real thing from a legitimate vendor. That practice puts the plaintiffs at risk of precisely the sort of negative outcomes that their expert evidence adduces. *See* Exhibit 6, ¶ 15.

239. Defendants' execution method violates 20 C.S.R. § 2220-2.400(9), which prohibits the compounding of (a) any drug products "that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products" or (b) any drug products that are "commercially available in the marketplace." The regulation provides as follows:

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[37]*See* Mo. Rev. Stat. § 536.140.2; *see also City of Valley Park v. Armstrong*, 273 S.W.3d 504, 506-507 (Mo. banc 2009) (explaining "non-contested cases" in which "the private litigant is entitled to challenge the governmental agency's decision").

> (9) Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound.

240. The state-official defendants have joined hands with their undisclosed compounding pharmacy DD1 to obtain and administer a "compounded" version of pentobarbital. Defendants seek to custom-manufacture their own pentobarbital, which is to say, "essentially cop[y]" an FDA-approved drug, and then to execute prisoners with it. The violation is not merely technical. It places the plaintiffs at risk of harm cognizable under the Eighth Amendment and Mo. Const. art. I, § 21, because the non-FDA-compliant substance is not reliably potent, pure, and effective. *See* Exhibit 6, ¶¶ 8-15.

241. FDA-compliant pentobarbital is "commercially available."

242. The state regulation 20 C.S.R. § 2220-2.400(9) applies to the defendants. It makes it illegal to "copy" an FDA-compliant drug whether it is "commercially available" or not. It prohibits the

compounding of "commercially available" drugs or the compounding of drugs that are "essentially copies" of FDA-approved drugs.

243. FDA-compliant pentobarbital is widely available "in the marketplace," 20 C.S.R. § 2220-2.400(9), to practitioners who seek to administer it for legitimate medical purposes.

244. The purpose of the rule is to protect those who receive the substances in question from dangerous and otherwise non-FDA-compliant drugs. That danger persists whether or not the legal drugs are "commercially available" to executioners.

245. The new protocol also violates the prescription requirement of 20 C.S.R. §§ 2220-2.400(9), (10) & (12). "The compounding of any drug product to be sold without a prescription is prohibited." *Id.* § 2.400(10). Compounding pharmacies must maintain "sufficient documentation" of their prescription records, which must reflect whatever specific medical need justified a particular variation of a particular "commercially available compound" for a particular patient. *Id.* § 2.400(9).

246. Assuming that M3 is the "practitioner" for the purpose of the transfer to be even arguably permitted by the foregoing regulations, he

or she is not a "prescriber," performing executions is not "in the course of professional practice" for a physician, and M3's victim is not a "patient."

247. Consequently, the protocol violates all three of the foregoing state regulations.

248. Defendants have revealed a purported "prescription" for the "patient" to receive compounded pentobarbital, and the state attached heavily redacted copies of that "prescription" to a November 15, 2013, filing in the Missouri Supreme Court. *See* Doc. No. 157-7; Exhibit 7 to this complaint at 1-2.

249. The "prescription" the defendants have tendered is not a prescription at all.

250. The ***federal*** regulation 21 C.F.R. § 1306.04(a) requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." A prescription is a medical practitioner's clinical judgment that a particular drug will appropriately treat a particular medical issue. A prescription issued without such a clinical judgment is no prescription at all, and in the

absence of a valid prescription, defendants' actions violate the Controlled Substances Act and the Food, Drug and Cosmetics Act by dispensing and administering a controlled substance. See 21 U.S.C. § 829(b); 21 U.S.C. § 353(b). Such state action violates the Supremacy Clause. U.S. Const. art. VI, cl. 2.

251. Here, the plaintiffs have no medical need for compounded pentobarbital; the only "need" for the compounded drug arises from the fact that defendants cannot obtain the real drug from legitimate channels.

252. The "prescriptions" attached to the State's pleading before the Missouri Supreme Court and shown in exhibits to this complaint are therefore ineffective, as well as multiple counts of a federal crime.[38]

253. In the previous iterations of the post-*Taylor* protocol, and in the protocol that the Eighth Circuit eventually approved in *Taylor*, the defendants did not obtain a prescription for the deadly drugs du jour.

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[38]*See, e.g.*, 18 U.S.C. § 841(a). *See, e.g., United States v. John Maye*, *http://www.democratandchronicle.com/story/news/local/2013/10/13/rochester-doctor-convicted-of-illegally-dispensing-drugs/2969053/* (last visited Dec. 3, 2013) (licensed physician convicted of illegal drug distribution for prescribing without legitimate medical reason).

They have not supplemented their discovery response to indicate that they would do so for the compounding-pharmacy product they represent to the Court to be pentobarbital.

254. Among the earliest of the foregoing Sunshine Law responses include a "Professional Medical Services Agreement" that includes the following language: "Upon request from the Department, Contractor will provide the Department with the requested prescriptions for the drug pentobarbital in the name of the offender to be executed." Exhibit 9 at 10. Defendants' response to plaintiffs Bucklew and M.A. Taylor includes copies with a background repeating the word "illegal" in the background that purport to be copies of a "prescription" for pentobarbital. Exhibit 13 at 25-26. Defendants had previously used the same or substantially the same document offensively in the Missouri Supreme Court, and the plaintiffs presented it to this Court as an exhibit to the reply in support of their motion to stay the execution of Mr. Franklin.[39] In the same response, the page after the heavily-redacted copy of the DD1's license is a heavily-redacted copy of the

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[39]Doc. No. 157-6, which for the reader's convenience the plaintiffs submit as Exhibit 7 to this complaint.

contract prescriber's license, showing that he or she is not in fact an M.D. but an osteopath. Exhibit 13 at 8-9.

255. By using the contents of the foregoing ostensible responses to four Sunshine-Law requests as admissions, the plaintiffs do not relinquish or abandon the claim to performance of the defendants' duties under the Sunshine Law.

256. In the first of the responses, the defendants provided the initial order dated October 21, 2013, for the deadly drug they have used and intend to use again, which referred to it as "phenobarbital." Exhibit 9 at 8. In this response, the defendants also included a version of the order, manually changed—ten days later—to read "pento" where the original had read "pheno". *Id.* at 12. Subsequent versions of responses to Sunshine-Law requests did not contain the original, mistaken, order that had sat in defendant DD1's inbox for ten days. Exhibits 10-13.

257. Under the facts and circumstances of this case, denial of the remedy Mo. Rev. Stat. § 536.140 tenders to the plaintiffs would be arbitrary.

258. Under the facts and circumstances of this case, the remedy to which Mo. Rev. Stat. § 536.140 entitles the plaintiffs relates to the quantum of punishment on criminal convictions.

Invasion of Freedom of Expression

259. Associations of health-care professionals, individual health-care professionals, and suppliers of precursor chemicals have a cognizable interest in policing the conduct of individuals and companies in the practice areas of the foregoing associations, professionals, and manufacturers.

260. It was such an interest that led the FDA-compliant manufacturer of propofol to announce its policy against supplying its product for use in executions.

261. It was such an interest that led the FDA-compliant manufacturer of pentobarbital to withhold its product for use in executions.

262. In addition, the public has a cognizable interest in learning the quality of the goods and qualifications of the persons involved in the execution of persons in their name.

263. American government is founded on the principle that governments derive their just powers from the consent of the governed.

264. Freedom of expression exists in large part to facilitate the working of the will of the people, *i.e.*, the ongoing consent of the governed to what the temporary occupants of public office are doing in their name.

265. Under the view of government underlying our Constitution, a policy whose implementation in fact the state cannot defend in the free marketplace of ideas is a policy it should not be pursuing in the first place.

266. The Supreme Court has held that the Eighth Amendment "'must draw its meaning from the evolving standards of decency that mark the progress of a maturing society.'"[40]

267. It is only through dissemination of knowledge about the processes of lethal injection that society can show what its "evolving standards of decency" are with respect to it. A temporary majority of elected officials could not legally freeze these standards by making it

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[40]*Atkins v. Virginia,* 536 U.S. 304, 311-12 (2002) (quoting *Trop v. Dulles,* 356 U.S. 86, 101 (1958).

illegal to express oneself about the practice of capital punishment or the method their executive officials and employees choose for carrying it out.

268. At the very least, the officials making the policy but concealing the details they know the health professions and related industries and the general public alike would find unseemly cannot say that their policy is consistent with "the evolving standards of decency that mark the progress of a maturing society."

269. As to lethal injection in particular, the question whether any given means of performing it conforms to "the evolving standards of decency that mark the progress of a maturing society" depends on more than speech by citizens. Whether a given substance or a given procedure will cause excruciating pain depends on the raw materials from which it is manufactured, the details of its manufacture, the incidents of its procurement, the background and training of its end-users, the execution team, and the other factors that the defendants are denying this Court, the plaintiffs, the health professions, the pharmaceutal manufacturers, and the public generally.

270. In order to decide what to think and what to say, people and their advocacy institutions need the information on the basis of which to form opinions, whether factual or normative.

271. Denying the public the information it needs to judge whether the officials' actions are consistent with the standards of society has the same effect as denying the people the right to express their judgments about the actions of these officials. It is a form of thought control.

272. If allowed, it would artificially freeze the standards that the Supreme Court envisions as evolving.

273. Concealing the identities of manufacturers, suppliers, and others involved in supplying the deadly drugs that the actual "execution team" has used and intends to use to kill the plaintiffs prevents the people from judging whether the method the defendants are using at any given moment conforms to the people's standards of decency.

274. Concealing the identities of manufacturers, suppliers, and others involved in supplying the deadly drugs that the actual "execution team" has used and intends to use to kill the plaintiffs prevents the suppliers' associations, customers, and prescribing or referring physicians from censuring or boycotting them.

275. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, concealing their identities unreasonably restricts the federal and state government from charging them with criminal offenses and their respective associations and colleagues from de-certifying or otherwise censuring them or boycotting them.

276. Concealing the identities of manufacturers, suppliers, and others involved in supplying the deadly drugs that the actual "execution team" has used and intends to use to kill the plaintiffs sweeps beyond any arguable necessity to protect the safety of individual executioners.

277. In January 2007, the *St. Louis Post-Dispatch* published the name of an immediate former leader of the "execution team," and no cognizable harm has come to him as a result of it in spite of the large numbers of deaths over which he presided and the flaws in his performance documented in the *Taylor* litigation.

278. In 2008, the *St. Louis Post-Dispatch* published the name of one member of the present execution team, and no cognizable harm has come to him as a result of it.

279. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, concealing the identities of the health-care professionals who actually perform the executions sweeps beyond the practical need to protect their safety.

280. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, the practical reason for concealing the identities of the ostensible health-care professionals who actually perform the executions is to prevent them from being de-certified by the boards on whose certification the defendants rely in making arguments to courts and the public.

281. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, any marginal contribution the nondisclosure of the names of the regulated health-care professionals who choose to participate in

executions would make toward their personal safety is not proportionate to the violation of freedom of expression it entails.

282. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, protecting the supply chain of deadly drugs and the veneer of board-certification for its executioners is not a compelling state interest sufficient to override the fundamental right of freedom of expression.

283. As applied to manufacturers, suppliers, and others involved in supplying the deadly drugs that the actual "execution team" has used and intends to use to kill the plaintiffs, protecting the supply chain of deadly drugs and the veneer of board-certification for its executioners is not a compelling state interest sufficient to override the fundamental right of freedom of expression.

284. Denying the public and all others concerned the information about these chemicals is not the least invasive means of reconciling the dealers' and licensed executioners' fear of retaliation with the public interest in a robust debate about their choices and a correct resolution of the factual questions it entails.

285. Denial of the right of associations of health-care providers and legitimate manufacturers, individual health-care providers and manufacturers, and consumers to exercise suasion over or withhold their custom from those members of the health-care community that choose to be executioners or to supply executioners contributes to the likelihood that the products and the performance involved in executions are of low quality by enabling the existence of companies and practice of individuals who do not adhere to the standards of their respective professions and trades.

286. As the objects or involuntary consumers of the products and performance of the currently incognito suppliers, compounder, "laboratory," and health-care professionals, the plaintiffs are among the intended beneficiaries of public knowledge of the identities of these entities and persons.

287. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, the plaintiffs themselves have a right to find out the information which Mo. Rev. Stat. § 546.720.2-4 would deny them. At a minimum,

this right is incident to their right of access to the courts. *Cf.* para. 67, *supra*. Insofar as the Supreme Court envisions the cognizable standards of decency to grow from society rather than from any given government official, employee, or contractor, they are also beneficiaries of diffusion of knowledge among the public and the health-care professions and industries about the actual practice of lethal injection and about the characteristics of the companies from which the defendants obtain the deadly drugs with which the defendants intend to kill them. In addition to their attorneys' efforts on their behalf in the courts, the plaintiffs have a right to communicate with relatives, friends, and the public generally to advocate their own interests.

288. More profoundly, they have a right to do so whether or not they can succeed in showing that the latest specifics of the defendants' plan for performing lethal injections on them are unconstitutional. It is profoundly consequential to the dignity of these human beings that they know by what means their government is planning their demise. If they must anticipate a ghastly death as a result of purchasing bootleg drugs from only nominally regulated processors who obtain raw materials from Communist China and other less developed countries—

because reputable suppliers will not sell to contract killers—the plaintiffs should not be fooled along with the electorate into thinking that they would simply be put to sleep. Like voters and health-care professionals, their right to freedom of expression depends on their knowledge of the facts the defendants seek to keep hooded.

Claims for Relief

Count I: Infliction of Cruel and Unusual Punishments

289. Plaintiffs restate and reallege the premises in paras. 1-116.

290. Defendants' use of what they represent to be pentobarbital from an undisclosed compounding pharmacy or compounding pharmacist as set forth in their latest protocol creates a substantial risk of severe pain or an objectively intolerable risk of severe pain.[41]

291. Defendants' recent, last-minute ostensible change of practice in respect to the use of central line access when it is not clinically indicated is not reliable enough in the absence of a judicial finding and order to remove the pre-existing substantial risk of severe pain or an objectively intolerable risk of severe pain resulting from the longstanding practice of its use by default.

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[41]*Baze v. Rees*, 553 U.S. at 52 & n.3 (Roberts, C.J.).

292. Defendants' intended actions as set forth in this Count I violate the Cruel and Unusual Punishments Clauses of Mo. Const. art. I, § 21, and of the Eighth Amendment to the United States Constitution, as applied to the states by its Fourteenth Amendment, and enforceable through 42 U.S.C. § 1983.

Count II: Ex Post Facto Law Violation

293. Plaintiffs restate and reallege the premises in paras. 1-126.

294. Defendants' intended use of compounding-pharmacy pentobarbital as set forth in their new protocol involves the infliction of a greater quantity of pain and suffering and a greater likelihood of harm than existed under pre-existing law.

295. The facts set forth in this complaint exceed the showing of a "significant risk of an increased punishment."[42]

296. For these reasons, the defendants' intended routine use of central line access and of compounding-pharmacy pentobarbital as set forth in their new protocol violates the Ex Post Facto Clauses of Mo. Const. art. I, § 13, and U.S. Const. art. I, § 10, as enforceable against the states through the Fourteenth Amendment and 42 U.S.C. § 1983.

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[42] *Garner v. Jones*, 529 U.S. 244, 255 (2000).

Count III: Violation of Separation of Powers

297. Plaintiffs restate and reallege the premises in paras. 1-145.

298. The Missouri method-of-execution statute purports to confer on defendant Lombardi power to select the "manner of inflicting the punishment of death" by either lethal gas or lethal injection.

299. In purporting to add a either ***company*** or a ***compounding*** pharmacist to the "execution team"—which would insulate from discovery and other fact-finding the ***source and nature*** of the substances to be used in a form of execution uniquely dependent on their provenance—and would thereby to add a new level of secrecy to the method of execution, defendant Lombardi has gone beyond the executive branch's discretion to implement the statutory direction to exercise a law-making power that the General Assembly declined to confer on him.

300. In the alternative, if defendant Lombardi is acting within the meaning of the statute, the statute itself is a legislative violation of the state's constitutional guaranty of separation of powers.

301. In either event, the defendants' intended actions as set forth in this Count III violate the separation-of-powers guaranty of Mo. Const. art. II, § 1.

302. This Court has the authority to address this claim under the Court's pendent jurisdiction, particularly in light of the fact that the defendants removed this action from state to federal court over the plaintiffs' objections.

Count IV: Deprivation of Liberty Without Due Process of Law

303. Plaintiffs restate and reallege the premises in paras. 1-175.

304. Defendants' conduct in obtaining execution dates before the plaintiffs have had a reasonable opportunity to seek and complete adversary proceedings denies the plaintiffs a day in court on their underlying federal and state constitutional claims concerning their execution protocols.

305. The foregoing denial of an effective remedy for the deprivation of the plaintiffs' civil rights violates 42 U.S.C. § 1983.

306. The foregoing de facto denial of notice and an opportunity to be heard in federal court violates the Due Process Clauses of the Fifth

and Fourteenth Amendments of the United States Constitution and Mo. Const. art. I, § 10, and the First Amendment and Mo. Const. §§ 8-9.

307. The foregoing changes to the defendants' execution protocol creates uncertainty which enhances the anxiety and suffering that the plaintiffs will experience prior to and during their executions. That unjustifiably enhanced punishment violates the Cruel and Unusual Punishments Clause of the Eighth Amendment and Mo. Const. art. I, § 21, as well as the Ex Post Facto Clauses of Mo. Const. art. I, § 13, and U.S. Const. art. I, § 10.

Count V: Denial of Equal Protection and Due Process

308. Plaintiffs restate and reallege the premises in paras. 1-218.

309. Defendants' execution protocol is binding law of the State of Missouri, and it creates cognizable life, liberty, and property interests in the plaintiffs to expect that the defendants will strictly follow their execution policies and protocol, and cognizable life, liberty, and property interests in the plaintiffs' actually receiving the benefit of the defendants' strictly following their execution policies and protocols in the course of their respective executions.

310. Defendants have no discretion whether to strictly follow their execution protocol and policies; adherence to the protocol and policies is mandatory.

311. These interests are rights vested in a small class of individuals that have a legitimate claim of entitlement to expect and receive strict application of the defendants' execution policies and procedures.

312. Plaintiffs, as condemned inmates subject to a death sentence under Missouri law, are the intended beneficiaries of the state-law-created guarantees and procedural safeguards represented by defendants' execution protocol and policies.

313. These plaintiffs' interests arising under state law are protected as rights under the substantive and procedural elements of the Due Process Clause of the Fourteenth Amendment.

314. Defendants, having granted the plaintiffs interests in expecting and receiving an execution that strictly complies with the written execution protocol, may not deprive the plaintiffs of those rights in violation of procedural and substantive due process under the Fourteenth Amendment.

315. Defendants' denial of the plaintiffs' rights to expect and receive an execution that is in strict compliance with the written protocol, especially in the circumstances such as those demonstrated in the execution of Mr. Franklin, is arbitrary and shocks the conscience.

316. The individual deviations and pattern of deviations or variations from the defendants' execution policy and written execution protocol engaged in by many of the actors involved, intentional or otherwise, including the egregious facts surrounding the execution of Mr. Franklin, point to an unacceptable risk of violating the plaintiffs' rights.

317. By what defendants include and exclude from their execution policy and protocol, and by their knowing disregard for critical portions of their protocol that, combined with the facts known to defendants at the time, would have prevented the execution of Mr. Franklin, the defendants' manifest deliberate indifference towards, or intentional deprivation of, the plaintiffs' state-law-created liberty, life, and property interests in expecting and receiving an execution that is in full and strict compliance with defendants' execution protocol and policies, which interests are protected as rights by the substantive and

procedural elements of the Fourteenth Amendment's Due Process Clause.

318. These rights are separate and distinct from the rights protecting the plaintiffs against cruel and unusual punishment as provided in the Eighth Amendment.

319. In all the foregoing ways, the defendants violate the plaintiffs' rights protected by the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

320. Plaintiffs have been or will be treated differently from other similarly situated individuals, burdening their fundamental rights as members of a class of persons subjected to a death sentence under Missouri law, without a compelling governmental interest, in violation of the guarantees of the Equal Protection Clause of the Fourteenth Amendment.

321. Plaintiffs have been or will be treated differently from other similarly situated individuals without any rational basis for the difference in disparate treatment as a class of one, irrationally and arbitrarily, in violation of the guarantees of the Equal Protection Clause

of the Fourteenth Amendment and the guaranty of Mo. Const. art. I, § 2.

Count VI: Unlawful Administrative Agency Action Remediable under Missouri Administrative Procedure Act

322. Plaintiffs restate and reallege the premises in paras. 1-258.

323. Defendant Lombardi's action in adding a company or corporation or a "compounding" pharmacist to the "execution team" under color of a protocol he purports to allow him to do so is in violation of constitutional provisions, most particularly Mo. Const. art. II, § 1, but also the Ex Post Facto Clauses of Mo. Const. art. I, § 13, and U.S. Const. art. I, § 10; the First Amendment to the United States Constitution and Mo. Const. art. I, §§ 8-9; the Due Process Clauses of the Fifth and Fourteenth Amendments and Mo. Const. art. I, § 10; and the Cruel and Unusual Punishments Clauses of the Eighth Amendment (as applied to the state through the Fourteenth) and Mo. Const. art. I, § 21.

324. Defendant Lombardi's action in adding a company or corporation or a "compounding" pharmacist to the "execution team" under color of the protocol is in excess of the statutory authority or

jurisdiction of the agency and unauthorized by law as set forth in the previous paragraph.

325. Defendant Lombardi's action in adding a company or corporation or a "compounding" pharmacist to the "execution team" under color of the protocol was taken through an "unlawful procedure or without a fair trial" and is arbitrary, capricious, unreasonable, and an abuse of discretion.

326. Defendants' threatened use of a compounding-pharmacy product they hold out to the Court as pentobarbital violates 20 C.S.R. § 2220-2.400(9), 20 C.S.R. § 2220-2.400(10), and 20 C.S.R. § 2220-2.400(12).

327. Defendants' solicitation, provision, and acceptance of a "prescription" for compounding-pharmacy pentobarbital, together with their act of dispensing and administering compounding-pharmacy pentobarbital without a legitimate clinical purpose to be served by that drug, violates the Controlled Substances Act and the Food, Drug & Cosmetic Act, as well as a binding regulation implementing both statutes. *See* 21 U.S.C. § 829(b); 21 U.S.C. § 353(b); 21 C.F.R.

§ 1306.04(a). As such, their conduct places them in violation of the Supremacy Clause, U.S. Const. art. VI, cl. 2.

328. The foregoing violations inherent in defendant Lombardi's action render him amenable to declaratory relief under Mo. Stat. Rev. § 536.140 and under this Court's pendent jurisdiction. *Cf.* para. 302.

329. Denial of the remedy tendered by section 536.140 would violate the Due Process Clause of the Fourteenth Amendment.

Count VII: Violation of First Amendment and Mo. Const. art. I, § 8-9

330. Plaintiffs restate and reallege the premises in paras. 1-288.

331. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, denial of the identities of licensed health-care professionals who choose to participate in executions violates the right of patients, colleagues, professional associations, and the public not to patronize them or to certify them in spite of their violation of professional norms.

332. Denial of the identities of suppliers, manufacturers, testers, and other commercial enterprises that choose to participate in executions violates the right of patients, colleagues, trade and

professional associations, and the public not to patronize them or to recognize them in spite of their violation of professional norms.

333. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, denial of the identities of licensed health-care professionals, suppliers, manufacturers, testers, and other commercial enterprises that choose to participate in executions violates the right of the plaintiffs, the professions, and the public to learn the facts necessary to evaluate the behavior of the government in respect to lethal injection.

334. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal law, protection of unlawful retaliation against health-care professionals is a pretextual ground for violating the freedom of expression of the plaintiffs, the health-care professions and industry, and the public.

335. At least in the absence of a showing that licensed health-care professionals are personally and directly engaging in the process of carrying out an execution, and are not thereby violating the criminal

law, concealing the identities of licensed health-care professionals, suppliers, manufacturers, testers, and other commercial enterprises that choose to participate in executions is not narrowly tailored to serve a compelling state interest.

336. In purporting to conceal this information, Mo. Rev. Stat. § 546.720.2-4 violates the First Amendment to the Constitution of the United States, made applicable to the states by the Fourteenth Amendment, and Mo. Const. art. I, §§ 8-9.

Prayer for Relief

1. Plaintiffs request a declaratory judgment that carrying out a lethal injection using the October 18, 2013, protocol relying on pentobarbital as the lethal agent violates—

I. the Cruel and Unusual Punishments Clauses of Mo. Const. art. I, § 21, and of the Eighth Amendment to the United States Constitution, as applied to the states by its Fourteenth Amendment;

II. the Ex Post Facto Clauses of Mo. Const. art. I, § 13, and U.S. Const. art. I, § 10;

III. the separation of powers guaranty of Mo. Const. art. II, § 1;

IV. 42 U.S.C. § 1983; the Due Process Clause of the Fifth Amendment the United States Constitution; the Due Process Clause of the Fourteenth Amendment and Mo. Const. art. I, § 10; the First Amendment and Mo. Const. art. I, §§ 8-9; and the Cruel and Unusual Punishments Clauses of Mo. Const.

art. I, § 21, and of the Eighth Amendment to the United States Constitution, as applied to the states by its Fourteenth Amendment;

V. the Equal Protection Clause of the United States Constitution, and Mo. Const. art. I, § 2, and the Due Process Clause of the United States Constitution and Mo. Const. art. I, § 10;

VI. Mo. Const. art. II, § 1; the Ex Post Facto Clauses of Mo. Const. art. I, § 13, and U.S. Const. art. I, § 10; the First Amendment to the United States Constitution and Mo. Const. art. I, §§ 8-9; the Due Process Clauses of the Fifth and Fourteenth Amendments and Mo. Const. art. I, § 10; the Cruel and Unusual Punishments Clauses of the Eighth Amendment (as applied to the state through the Fourteenth) and Mo. Const. art. I, § 21; 20 C.S.R. § 2220-2.400(9), (10) & (12); 21 U.S.C. § 829(b); 21 U.S.C. § 353(b); 21 C.F.R. § 1306.04(a); and the Supremacy Clause, U.S. Const. art. VI, cl. 2, all as cognizable through the Missouri Administrative Procedures Act; and

VII. the First Amendment to the United States Constitution, made applicable to the states by the Fourteenth, and Mo. Const. art. I, §§ 8-9.

2. Plaintiffs request an injunction commanding the defendants not to carry out a lethal injection as described in the October 18, 2013, protocol on account of the violations of state and federal law set forth in the foregoing paragraph.

3. Plaintiffs seek this Court's order granting them reasonable attorney fees as well as the costs of suit, and such further relief as this Court deems just and proper.

WHEREFORE, the plaintiffs pray the Court for its order and judgment as aforesaid.

Respectfully submitted,

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Certificate of Service

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